Iowa Board of Pharmacy
Resident and Nonresident Pharmacy Application Instructions

Complete the attached Iowa Board of Pharmacy application for pharmacy license. Be sure to check the box for the relevant application type (New, Name Change, Ownership Change, License Type Change or Location Change).

A new pharmacy location in Iowa requires an on-site inspection by an authorized agent of the board. The application for pharmacy license must be submitted to the Board at least 14 days prior to the anticipated inspection.

Failure to submit a complete and timely application will delay the processing of your application.

An incomplete application for licensure will only be maintained for a maximum period of 6 months. Failure to submit all required information within 6 months of submission of the original application, including completion of a successful on-site inspection when required, will result in the application becoming null and void and any fees submitted with the application are forfeited and will not be transferred or refunded. Submit the completed application, including the instruction check lists, all attachments, and a check in the appropriate amount made payable to the Iowa Board of Pharmacy to:

Iowa Board of Pharmacy
400 SW 8th St. Ste. E
Des Moines, IA 50309-4688

LICENSE CHANGES – a name change, ownership change, license type change or location change requires the submission of a completed application and fee.

PIC Changes (permanent and temporary) - requires the submission of the PIC change application or Temporary PIC change notification form. **DO NOT USE THIS APPLICATION**

Name Change – A change of the name under which the pharmacy is doing business requires the submission of a completed application and fee prior to the change of name. **Nonresident Pharmacies** - A change of the pharmacy name under which the pharmacy is doing business requires the submission of a completed application and fee within ten days after issuance by the home state regulatory authority of a license bearing the new name.

Location Change - A change of pharmacy location requires the submission of a completed application and fee prior to the change of location. A pharmacy undergoing a change in location is required to notify patients of the change in accordance with 657 IAC 8.35(7)"d". A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in 657 IAC 8.35(4). **Nonresident Pharmacies** – A change of location requires the submission of a completed application and fee within ten days after issuance by the home state regulatory authority of a license bearing the new address.

Ownership - A change in ownership requires the submission of a completed application and fee prior to the change in ownership. A change of ownership occurs when the owner listed on the pharmacy's most recent pharmacy license application changes or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy's most recent pharmacy license application. A pharmacy undergoing a change in ownership is required to notify the Board, the pharmacist in charge and patients of the change in accordance with 657 IAC 8.35(7).

License type - A change in pharmacy license type requires the submission of a completed application and fee prior to the change in license type. A pharmacy changing license type shall notify the pharmacist in charge and patients of the change in accordance with 657 IAC 8.35(7).

Nonresident Pharmacies Only:

New Applicants - The inspection requirements identified in rule 657 IAC 19.2 must be satisfied prior to submitting an application for licensure.

Toll-free telephone number - The pharmacy's toll-free telephone number is required to allow patients to speak with a pharmacist who has access to patient records at least six days per week for a total of at least forty hours.

Pharmacist in charge (PIC) - Every nonresident pharmacy is required to have a PIC who is either currently licensed to practice pharmacy in Iowa or who is registered with the Board in accordance with rule IAC 657 19.3. If your PIC is not currently licensed to practice pharmacy in Iowa or is not registered with the Board, your PIC must apply for registration as a nonresident pharmacy PIC. The PIC must complete the Board's training module, "Iowa Pharmacy Law Bootcamp: Education for Iowa Nonresident Pharmacists," prior to submission of the application. The training is free and can be found on the Board's website at, https://pharmacy.iowa.gov/.

Iowa Prescription Monitoring Program (PMP) - Nonresident pharmacies are required to report to the PMP all prescriptions for Schedules II, III, and IV controlled substances dispensed to patients located in Iowa, including submission of zero reports when no reportable prescriptions are dispensed during a reporting period. Please be aware of the reporting requirements described in 657 IAC Chapter 37 of the Board's rules and the Iowa Data Reporting Manual.

All application fees are non-refundable and non-transferrable.

Initial Application Fees	
Initial Pharmacy License Application Fee	$135.00
Initial Controlled Substance Act Registration (CSAR) Application Fee *(a pharmacy that handles controlled substances within or into Iowa is required to obtain a CSAR)*	$90.00
Nonresident Pharmacies Only – Nonresident PIC Registration Fee *(a PIC registration is only required if the PIC does not hold a current/active Iowa pharmacist license or a current/active Nonresident PIC registration)*	$75.00
License Change Application Fees – Changes to the name, ownership, license type, and/or location requires the submission of a completed application and applicable fee(s). Multiple changes to a license within the same application require only a single fee for the license and a single fee for the registration(s). See the above instructions for additional information.	
Pharmacy License Application Fee	$135.00
CSAR Application Fee (if applicable)	$90.00
Late License Change Application Fees – These fees are due for applications that are not timely submitted, but are submitted within 30 days of the required submission period. These fees include the timely application fee and penalty fee and are **not** in addition to the previously identified fees.	
Pharmacy License Application including Penalty Fee	$270.00
CSAR Application including Penalty Fee	$180.00
Reactivation Fee – These fees are due for applications submitted more than 30 days after required submission period. These fees include the application fee and penalty fee and are **not** in addition to the previously identified timely application fee or application and penalty fee.	
Pharmacy License Reactivation Fee	$540.00
CSAR Reactivation Fee	$360.00

APPLICATION CHECKLIST	
RESIDENT AND NONRESIDENT PHARMACY	
Proof of Accreditations	☑YES ☐N/A
DEA Registration	☑YES ☐N/A
List of All Licenses / Permits / Registrations in Other States	☑YES ☐N/A
FDA 483s, Warnings Letters, and Responses to each	☑YES ☐N/A
List of Disciplinary Actions by Licensing Authorities and Documentation of Final Disciplinary Orders	☑YES ☐N/A
List of Final Denial Orders by Licensing Authorities and Documentation of Final Denial Orders	☑YES ☐N/A
List of Each Criminal Conviction and Court Records of the Conviction(s)	☑YES ☐N/A
RESIDENT PHARMACY ONLY	
Names, titles, and license/registration numbers for all pharmacists, pharmacist interns, technicians, and pharmacy support persons currently employed or practicing at this location.	☐YES
NONRESIDENT PHARMACY ONLY	
PIC License issued by Applicant's Home State	☑YES ☐N/A
Home State Pharmacy License / Permit / Registration	☑YES
Most Recent Inspection Report as specified in Iowa Code 155A.13A(1)(c)	☑YES ☐N/A
Prescription Label Showing Toll-Free Phone Number	☑YES

Phone: (818) 876-3060
Fax: (818) 876-3010
E-mail: info@woodlandhillspharmacy.com

Woodland Hills Pharmacy
20631 Ventura Blvd Ste 305
Woodland Hills, CA 91364

June 9, 2020

Iowa Board of Pharmacy
400 SW 8th St. Ste E
Des Moines, IA 50309-4688

To whom it may concern:

Please find enclosed our application for a non-resident pharmacy license in Iowa. We would like to make a few comments on our application, especially regarding disciplinary actions and FDA inspections.

1. **California Board of Pharmacy probation:** Our pharmacy was placed on probation by the California Board of Pharmacy effective March 12, 2018 through March 21, 2022. A copy of this order is included as well as an explanation in our summary of disciplinary actions. We would like to note that the majority of states we are licensed in have decided to either institute reciprocal probation mirroring the California order or take no action regarding this matter. The pharmacy is in complete compliance with all requirements of the probation in California and other states. The probation requires regular inspections from the California Board of Pharmacy as well as an independent consultant. Recent inspection reports are included.

2. **NABP Accreditation:** Our pharmacy is accredited by NABP's compounding pharmacy program. Our most recent VPP inspection was March 2020 and a copy of the inspection report is included.

3. **FDA 483s and Warning Letter:** All FDA matters have been resolved, and the pharmacy has received closeout letters for two pending 483s and one warning letter. These closeout letters are included with the original inspection reports or letters. At present, there are no pending items of concern with the FDA.

Our pharmacy has worked hard at improving itself over the years. We hold our compounding pharmacy services to the highest quality standards, and are compliant with all laws and regulations. The disciplinary actions we have received have helped us raise our standards and better serve patients. We seek to serve patients in Iowa with high quality compounded formulations customized to their needs, made at our accredited compounding pharmacy. We thank the Board for its consideration of our application and appreciate its time in reviewing our materials

Sincerely,

Steven Levin, RPh
Pharmacist-in-Charge
Woodland Hills Pharmacy

Iowa Board of Pharmacy
400 S.W. 8th St. Ste. E
Des Moines, IA 50309-4688
515-281-5944
https://pharmacy.iowa.gov/

RECEIVED
JUN 15 2020

APPLICATION FOR RESIDENT AND NONRESIDENT PHARMACY LICENSE

Please type or print legibly in ink. Applications submitted to change the license name, owner, license type, location must complete the "effective date of change" field(s). **Incomplete or illegible forms will delay the issuance of your license.**

APPLICATION TYPE		
New ☑ Anticipated Date of Opening: 09/01/2020	Name Change ☐ Effective Date of Change:	
Ownership Change ☐ Effective Date of Change:	License Type Change ☐ Effective Date of Change:	Location Change ☐ Effective Date of Change:

1. FACILITY TYPE			
General Pharmacy ☐	Hospital Pharmacy ☐	Nonresident Pharmacy ☑	
Limited Use Pharmacy – Correctional ☐	Limited Use Pharmacy – Nuclear ☐	Limited Use Pharmacy – Veterinary ☐	Limited Use Pharmacy – Other ☐

2. LICENSEE/APPLICANT INFORMATION			
A. Name of Applicant: *(Name in which pharmacy is doing business)*	WOODLAND HILLS PHARMACY		
Iowa License Number:		Federal Tax ID #:	[redacted]
Legal Name of Pharmacy:	ALGUNAS INC.		
Pharmacy's NABP e-Profile ID:	821758		
Name of Pharmacist in Charge (PIC):	Steven Levin		
Iowa Pharmacist License or PIC Registration Number:	NABP e-Profile ID: 462191		

If you do not have an NABP e-profile number, you may create one by going to nabp.pharmacy

B. Pharmacy Address *(physical location of pharmacy)*					
Street Address:	20631 Ventura Blvd			Suite #:	305
Address:					
City:	Woodland Hills	State:	CA	Zip Code:	91364

The phone number must be a direct number to the pharmacy

Telephone #:	855-876-3060	**Landline ■ Cell Phone# ☐** **If cell, will you accept text messages? ☐Y ☐N**
Alternate Phone#:	818-568-0033	**Landline ☐ Cell Phone# ■** **If cell, will you accept text messages? ☐Y ☐N**

The email address must be a direct email to the pharmacy or PIC

Email Address:	woodlandhillspharmacy@gmail.com	**Fax #:**	818-876-3010
Web Site:	woodlandhillspharmacy.com		
Mailing Address ***(where all correspondence regarding licensure will be sent if other than pharmacy's physical address)*****:**			
Street Address:	Same as pharmacy's physical address	**Suite #:**	
Address:			
City:		**State:**	**Zip Code:**

C. Pharmacy Ownership *A change of ownership occurs when the owner listed on the pharmacy's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy's most recent application. A change to a type of corporation is an ownership change if the name of the corporation changes in any respect (i.e. ABC, Inc. changes to ABC, LLC).*

Owner Name:	Steven Levin		
Owner Address:	20631 Ventura Blvd Ste 305		
City, State, Zip:	Woodland Hills		
Owner Phone Number:	855-876-3060	**Fax:**	818-876-3010
Email:	woodlandhillspharmacy@gmail.com		

Type of Ownership:

Sole Proprietorship	☐	**Partnership**	☐	**C Corporation**	✓
S Corporation	☐	**LLC**	☐	**Government**	☐

Date Established:	02/04/2011
State of Incorporation (if applicable):	02/04/2011

3. FACILITY OPERATIONS

A. Hours of Pharmacy Operation *(example: 8:00 a.m. to 5:00 p.m. or CLOSED)*

Sunday	CLOSED	**Thursday**	8:00 am to 4:30 pm
Monday	8:00 am to 4:30 pm	**Friday**	8:00 am to 4:30 pm
Tuesday	8:00 am to 4:30 pm	**Saturday**	CLOSED
Wednesday	8:00 am to 4:30 pm		

B. Type of Pharmacy Services *(check all that apply)*			
General Dispensing		Central Rx Processing	
Hospital		Mail Order Only	✓
Central Rx Filling		Home Infusion	
Nuclear		Care Facility Filling	
Care Facility Consulting		Emergency Drug Kits	
Unit Dose		Home Health/DME	
OTC Pseudoephedrine Sales		Exempt CV Dispensing	
Prepackaging		EMS	
Collaborative Practice Agreements (CPA)		CPA Explanation	
Technician Product Verification		Prescription Delivery/Mail-outs/Mail Order	
Medication Therapy Management		Statewide Protocol-Naloxone	
Statewide Protocol-Immunization		Statewide Protocol-Nicotine Replacement	
CLIA-Waived Testing		Compliance Packaging/MedPaks	
Noncontrolled Substance Collector		DEA-registered Controlled Substances Collector	
Naloxone Standing Order		Other (please explain):	

C. Populations Served					
Human	✓	Veterinary-companion animals		Veterinary-food producing animals	
Number of prescriptions dispensed into Iowa last year: *Nonresident pharmacies only*	0				

D. Compounding *(check all that apply)*					
Sterile High-Risk		Sterile Medium-Risk		Sterile Low-Risk	
Sterile Immediate Use		Sterile Hazardous Drugs		Sterile Anticipatory	
Sterile Shipping out of state		% of Sterile Compounded Preparations Shipped Out of State During the Previous Year:			
Sterile for patients in other facilities		Sterile Number of Facilities			
Number of sterile compounded preparations dispensed into Iowa last year:					
Non Sterile Simple	✓	Non Sterile Moderate	✓	Non Sterile Complex	✓
Non Sterile Anticipatory		Non Sterile Hazardous Drugs	✓	Prescriber Office Use	
Pursuant to Patient Specific Rx	✓				
Number of non-sterile compounded preparations dispensed into Iowa last year:	0				

E. Pharmacy Accreditations *(attach proof of any accreditations)*							
VIPPS	☐	ACHC	☐	DMEPOS	☐	None	☐
PCAB	☐	JCAHO	☐	VPP	☑	Other: NABP	

4. FDA INFORMATION	
Since your last application, has the pharmacy been inspected by the FDA:	☑ Yes ☐ No
If yes, date of most recent FDA inspection:	10/11/2018
Since your last application, has the FDA issued a 483? *(attach the FDA's documentation and your response to the FDA)*	☑ Yes ☐ No
Since your last application, has the FDA issued a Warning Letter? *(attach the FDA's documentation and your response to the FDA)*	☑ Yes ☐ No
Are you registered with the FDA as a 503(b) outsourcing facility?	☐ Yes ☑ No

5. CONTROLLED SUBSTANCES *(Attach copy of DEA registration, if applicable)*			
Do you handle controlled substances within or into Iowa? *If yes, a fee is required for new registrations and changes to licensee information (see instructions for additional information)*	■Yes ☐No		
DEA Registration #:	[redacted]	Expiration Date:	5/31/2021
Iowa CSA Registration #:		Expiration Date:	
Check schedules of controlled substances that you intend to dispense in or into Iowa:			
Schedule II Narcotic	☐	Schedule II Nonnarcotic	☐
Schedule III Narcotic	☐	Schedule III Nonnarcotic	☑
Schedule IV	☑	Schedule V	☑
Number of controlled substances prescriptions dispensed in or into Iowa last year:	0		
Number of opioid prescriptions dispensed in or into Iowa last year:	0		

6. CURRENT PHARMACY LICENSES, PERMITS, OR REGISTRATIONS IN OTHER STATES *(attach additional pages if necessary)*				
STATE	LICENSE / PERMIT / REGISTRATION NUMBER	ISSUE DATE	EXPIRATION DATE	STATUS
See attached				

The regulatory questions only require an affirmative answer if there has been a reportable offense specifically to the licensed location since the last application

7. DISCIPLINARY ACTIONS ***(new applicants must disclose all disciplinary actions described below; change applications must include information not previously reported and provided to the Board)***

A. Since your last application, has the pharmacy, any owner, or employee been disciplined by any licensing authority? Discipline includes, but is not limited to, citations, reprimands, fines, and license/registration restrictions, probation, suspension, revocation, or surrender.

☑ YES ☐ NO

Include a separate sheet of paper listing all disciplinary actions by any licensing authority against this pharmacy location and include documentation of any final disciplinary orders

B. Since your last application, has the pharmacy, any owner, or employee been denied a license by any licensing authority?

☑ YES ☐ NO

Include a separate sheet listing the final denial orders by any licensing authority against this pharmacy location and include documentation of any final denial orders.

C. Do you have any knowledge of any investigations, complaints, or charges pending against this pharmacy location before any licensing authority?

☐ YES ☑ NO

Include an explanation for any pending investigations, complaints, or charges.

8. CRIMINAL HISTORY ***(new applicants must provide a complete history; change applications must include information not previously reported and provided to the Board)***

A. Since your last application, has the pharmacy, any owner, or employee been convicted of or entered a plea of guilty, nolo contendere, or no contest to any crime related to prescription drugs, controlled substances, healthcare, or the practice of pharmacy in any jurisdiction? You must include all misdemeanors and felonies, even if adjudication was withheld by the court so that you would not have a record of conviction.

☑ YES ☐ NO

Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court records of the conviction(s)

9. SIGNATURE

I hereby swear or affirm under penalty of perjury that the information provided in this application is true and correct. I understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against my license.

Signature of Applicant or Designated Representative:	X
Printed Name and Title:	Steven Levin, Owner/Pharmacist-in-Charge
Date:	

NONRESIDENT PHARMACY ONLY:

1. HOME STATE PHARMACY LICENSE INFORMATION *(attach a copy of home state license, permit, or registration)*	
State:	California
License Number:	PHY50815
Original Date Issued:	02/01/2012
Expiration Date:	02/01/2021
Current Status:	Probation or practice restriction

2. REGISTERED AGENT					
Name:	Self				
Street Address:	20631 Ventura Blvd			**Suite #:**	305
City:	Woodland Hills	**State:**	CA	**Zip Code:**	91364

3. INSPECTION INFORMATION *(attach most recent inspection report which must comply with 657 IAC-19.2 which dictates specific inspection requirements)*		
Most Recent Inspection Performed by:		
Home State Licensing Authority ☐	**Iowa Board of Pharmacy** ☐	**Other Pre-Approved Entity:** ☑
Date of Most Recent Inspection:	3/12/20 VPP	

4. TOLL-FREE TELEPHONE NUMBER *(attach copy of label showing number)*:	
Toll-free telephone number:	(855) 876-3060
List Monday-Sunday hours of operation of toll-free telephone number:	8:00 am to 4:30 pm Monday - Friday 9:00 am to 12:00 pm Saturday
The pharmacy's toll free telephone number allows patients to speak with a pharmacist who has access to patient records at least six days per week for a total of at least forty hours.	☑ Yes ☐ No *(if no, your pharmacy does not qualify for licensure in Iowa)*

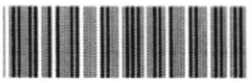
NABP ACCREDITED
COMPOUNDING PHARMACY

located at

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at www.nabp.pharmacy/programs/compounding.

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

12/17/2019 - 11/19/2020
Period of Accreditation



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WOODLAND HILLS PHARMACY
20631 VENTURA BLVD
STE 305
WOODLAND HILLS, CA 91364-9136

100926769 / 002997

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2021	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	04-04-2018

WOODLAND HILLS PHARMACY
20631 VENTURA BLVD
STE 305
WOODLAND HILLS, CA 91364-9136

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2021	$731

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	04-04-2018

WOODLAND HILLS PHARMACY
20631 VENTURA BLVD
STE 305
WOODLAND HILLS, CA 91364-9136

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Woodland Hills Pharmacy Licenses - Updated 6/8/20

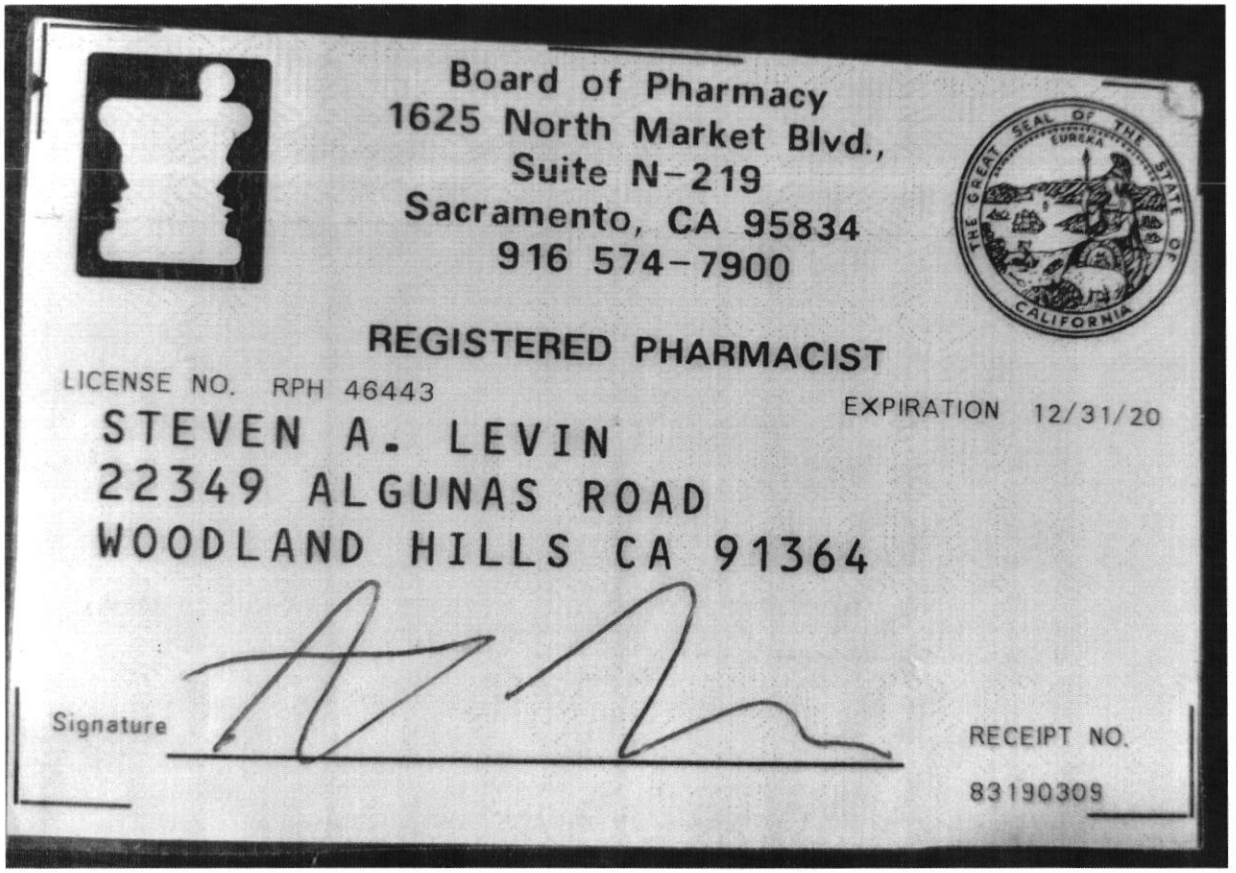
State	Permit Number	Exp Date
AZ	Y005879	10/31/21
CA	PHY50815	2/1/21
CO	OSP.0006236	10/31/20
CT	PCN.0002545	8/31/20
DE	A9-0001298	9/30/20
FL	PH 27035	2/28/21
IL	054.018358	3/31/22
IN	64001491A	12/31/21
KS	22-44690	6/30/21
LA	PHY.007093-NR	12/31/20
MA	NA	1/1/24
MD	P06088	Extended
MI	5301010166	06/30/20
MN	264242	06/30/21
MO	2013032004	10/31/21
NJ	28RO00088200	6/30/21
NM	PH00003691	12/31/21
NV	PH03028	10/31/20

Woodland Hills Pharmacy Licenses - Updated 6/8/20

State	Permit Number	Exp Date
NY	032218	7/31/22
OH	022341900	3/31/21
OK	99-7018	12/31/20
OR	RP-0003082	3/31/21
PA	NP001417	8/31/21
TN	5593	7/31/21
TX	28973	1/31/22
WA	PHNR.FO.60530804	5/31/21
WI	1369-43	5/31/22

Woodland Hills Pharmacy Staff

Name	Title	License
Steven Levin	Pharmacist-in-Charge	RPH 46443
Amit Sule	Pharmacist	RPH 54528
Lauren Fallieras	Pharmacist	RPH 65381
Reina Meza	Technician	TCH 135811
Edna Beteta	Technician	TCH 159883
Jennifer Stewart	Pharmacy Service Rep	TCH 165870
Massiel Figueroa	Pharmacy Service Rep	TCH 151376
Michelle Moreno	Pharmacy Service Rep	TCH 43442
Liu Iurecico	Clerk	N/A
Raun Lauderdale	Clerk	N/A
Jehovani Quijano	Shipping	N/A
Jody Levin	Finance Manager	N/A
Martin Loiselle	Manager	N/A



Board of Pharmacy
1625 North Market Blvd.,
Suite N-219
Sacramento, CA 95834
916 574-7900

REGISTERED PHARMACIST

LICENSE NO. RPH 46443

EXPIRATION 12/31/20

STEVEN A. LEVIN
22349 ALGUNAS ROAD
WOODLAND HILLS CA 91364

Signature

RECEIPT NO.
83190309

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Retail Pharmacy Permit

LICENSE NO. PHY 50815
RECEIPT NO. 93430191

VALID UNTIL FEBRUARY 01, 2021

WOODLAND HILLS PHARMACY
20631 VENTURA BLVD STE 305
WOODLAND HILLS CA 91364

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

9/10/19
9/10/19 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

Phone: (855) 876-3060
Fax: (818) 876-3010
Email: info@woodlandhillspharmacy.com

National Association of Boards of Pharmacy
ATTN: Verified Pharmacy Program
1600 Feehanville Drive
Mount Prospect, IL 60056

RE: Responses to VPP Inspection Report

Facility Name: Algunas Inc., DBA Woodland Hills Pharmacy
Address: 20631 Ventura Blvd Ste 305, Woodland Hills, CA 91364
eProfileID: 821758

To whom it may concern:

Please see the attached responses regarding the VPP inspection conducted at Woodland Hills Pharmacy on March 12, 2020. We have addressed all issues of non-compliance per the inspection report. In particular, note that we have removed from inventory all APIs of concern to the inspector, and have reviewed all BUDs to ensure they are assigned appropriately and based on established standards. We appreciate your time and review of our responses.

Sincerely,

Steve Levin, RPh
Owner, Pharmacist-in-Charge
Woodland Hills Pharmacy

Pharmacy Name: Algunas Inc. DBA Woodland Hills Pharmacy

Pharmacy Address: 20631 Ventura Blvd Ste 305 Woodland Hills, CA 91364

NABP Facility e-Profile ID: 821758

VPP Inspection Date: 3/12/2020

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	26	21.00	While grape seed extract has a C of A, we have decided that it will be removed from all compounds until there is assurance that it meets 503a criteria.	4/1/2020	N	
Updates/New SOPs or P&Ps	26	21.03	removed from all compounds until there is assurance that it meets 503a criteria.	4/1/2020	N	
Updates/New SOPs or P&Ps	26	21.04	TCA has been removed from inventory until we can obtain better assurance that it meets 503a criteria.	4/1/2020	N	
Updates/New SOPs or P&Ps	27	21.09	We will assign expiration date that is the lesser of 1 year or the expiration of the original container.	4/1/2020	N	
Updates/New SOPs or P&Ps	27	23.00	removed from all compounds until there is assurance that it meets 503a criteria.	4/1/2020	N	
Updates/New SOPs or P&Ps	28	29.00	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating
Updates/New SOPs or P&Ps	28	29.01	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating
Updates/New SOPs or P&Ps	28	32.00	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating
Updates/New SOPs or P&Ps	30	43.00	We have changed the excursion range to 68-77°F. Note there were no excursions outside this range despite the monitor being set for min 65.	4/1/2020	N	
Updates/New SOPs or P&Ps	30	43.03	We have changed the excursion range to 68-77°F. Note there were no excursions outside this range despite the monitor being set for min 65.	4/1/2020	N	
Updates/New SOPs or P&Ps	33	61.01	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating
Updates/New SOPs or P&Ps	33	61.10	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating
Updates/New SOPs or P&Ps	34	62.11	We will update all master formulas and worksheets with description.	4/1/2020	N	
Updates/New SOPs or P&Ps	33	61.12	We will update all master formulas and worksheets with description.	4/1/2020	N	
Updates/New SOPs or P&Ps	34	62.13	Duplicate label will be included except when batch is made for stock only.	4/1/2020	N	
Updates/New SOPs or P&Ps	35	70.00	We will update all master formulas and worksheets with description.	4/1/2020	N	
Updates/New SOPs or P&Ps	36	78.00	We have decreased the BUD on the master formulas to meet USP standards.	4/1/2020	Y	P-8.30 Beyond Use Dating

Pharmacy Name: Algunas Inc. DBA Woodland Hills Pharmacy

Pharmacy Address: 20631 Ventura Blvd Ste 305 Woodland Hills, CA 91364

NABP Facility e-Profile ID: 821758

VPP Inspection Date: 3/12/2020

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	36	75.00	We will update all master formulas and worksheets with description.	4/1/2020	N	
Updates/New SOPs or P&Ps	CAP Suppleme	29.01	We are scheduling next stability test for shipping for May 2020.	4/1/2020	N	

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	821758		**Inspection Information**
Legal Business Name:	Algunas Inc	**Day 1:**	3/12/2020
Doing Business As (DBA):	Woodland Hills Pharmacy	**Start Time: 24-hour format (13:00)**	8:15
Address:	20631 Ventura Blvd. Suite 305	**End Time: 24-hour format (13:00)**	16:20
City:	Woodland Hills	**Day 2:**	
State:	CA	**Start Time: 24-hour format (13:00)**	
Zip Code:	91364	**End Time: 24-hour format (13:00)**	
Telephone number:	855-876-3060	**Inspector Name:**	Susan Martin
Toll free number:	855-876-3010	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	818-876-3010	**Observer Name/Affiliation (if applicable):**	
Website:	Www.woodlandhillspharmacy.com	**Observer Name/Affiliation (if applicable):**	

Pharmacy Hours of Operation	**Check if 24/7** ☐		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			X
Monday	8:00	16:30	
Tuesday	8:00	16:30	
Wednesday	8:00	16:30	
Thursday	8:00	16:30	
Friday	8:00	16:30	
Saturday			X

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Steven Levin	Steve.levin123@gmail.com	462191
Nonsterile Compounding Supervisor	Amit Sule	Benzene69@gmail.com	144694
Sterile Compounding Supervisor	N/A	N/A	N/A
Hazardous Compounding Supervisor	Steven Levin	Steve.levin123@gmail.com	462191

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Steve Levin	Pharmacist in charge	Y
2	Amit Sule	Pharmacist	Y
3	Lauren Fallieras	Pharmacist	Y
4	Reina Meza	Technician	Y
5	Erick Murcia	Technician	Y
6	Edna Beteta	Technician	Y
7	Martin Loiselle	Marketing/IT	N/A
8	Jody Levin	Finance	N/A
9	Jen Stewart	Pharmacy Services Rep	Y
10	Lui Iurecico	Pharmacy Services Rep	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present. Also present - 4 Pharmacy Services Reps, who are also licensed technicians, and one shipping clerk.

Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
Pharmacy/CA BOP	Woodland Hills Pharmacy	Pharmacy/PHY 50815	2/1/2021
Federal/DEA	Algunas Inc.	[redacted]	5/31/2021
Pharmacy/AZ BOP	Woodland Hills Pharmacy	Pharmacy/Y005879	10/31/2021
Pharmacy/CO BOP	Woodland Hills Pharmacy	Pharmacy/OSP.0006236	10/31/2020
Pharmacy/CT BOP	Woodland Hills Pharmacy	Pharmacy/PCN.0002545	8/31/2020
Pharmacy/DE BOP	Woodland Hills Pharmacy	Pharmacy/A9-0001298	9/30/2020
Pharmacy/FL BOP	Woodland Hills Pharmacy	Pharmacy/PH 27035	2/28/2021

Inspector Notes: List states in which Non-Resident licenses are held. See attachment #1 for complete list of all other non-resident licenses. The CA license is for retail pharmacy, however it is primarily a closed door compounding pharmacy. It has a reception area where local customers can pick up prescriptions, however, only 1-2 customers come by per week.

Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
Attachment #1	Non-resident licenses held by Woodland Hills Pharmacy
Attachment #2	FDA 2018 inspection and response
Attachment #3	Invoice from Amazon for Grape Seed Extract Powder
Attachment #4	Compounding record for TCA 20%
Attachment #5	Preprinted prescription forms
Picture #1	Grape Seed Extract Powder by Bulk Supplements.com
Picture #2	TCA labeled not for food or drug use

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	3136 sq. ft	Total Pharmacists:	3
Nonsterile Compounding Room size:	400 sq. ft	Number of Compounding Pharmacists	2
Nonsterile Compounding powder hoods number:	2	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	176 sq. ft	Total Student Interns:	0
Nonsterile HD Compounding BSC/CACI hoods number:	1	Total Technicians:	6
Sterile Compounding Ante Room size:	0	Number of Compounding Technicians	3
Sterile Compounding Clean/Buffer Room size:	0	Of technicians, how many are certified?	3
Sterile Compounding Number LAFW hoods/areas:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	6
Negative Pressure Sterile HD Room size:	0	Ratio #tech:#RPh present at time of inspection:	3:3
Sterile HD Compounding Number of BSC hoods:	0	Total Pharmacist Hours Per Week:	100
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	240

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	100	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	1%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	95%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	15%	% Hazardous Drugs (HD) Orders	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
AK			
AL			
AR			
AZ	62	0	February 2020
CA	908	0	February 2020
CO	14	0	February 2020
CT	35	0	February 2020
DC			
DE	6	0	February 2020
FL	61	0	February 2020
GA			
HI			
IA			
ID			
IL	49	0	February 2020
IN	37	0	February 2020
KS	10	0	February 2020
KY			
LA	20	0	February 2020
MA	41	0	February 2020
MD	33	0	February 2020
ME			
MI	35	0	February 2020
MN	56	0	February 2020
MO	15	0	February 2020
MS			
MT			

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
NC			
ND			
NE			
NH			
NJ	31	0	February 2020
NM	33	0	February 2020
NV	9	0	February 2020
NY	94	0	February 2020
OH	46	0	February 2020
OK	9	0	February 2020
OR	28	0	February 2020
PA	28	0	February 2020
RI			
SC			
SD			
TN	14	0	February 2020
TX	142	0	February 2020
UT			
VA			
VT			
WA	62	0	February 2020
WI	12	0	February 2020
WV			
WY			
Other:			

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours per week.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	This pharmacy is on the third floor of an office building. The other businesses in this building are not associated with the pharmacy.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	Yes	woodlandhillspharmacy.com
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Amit Sule/Pharmacist; Lauren Fallieras/Pharmacist, Reina Meza/Technician, Jehovani Quijano (shipping clerk).
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Per the PIC, 25% are shipped to providers in California and 5% to providers in other states. The majority of the shipments are to dentists for administration in the office during procedures, and each compounded prescription is patient specific.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	They no longer distribute compounded products for office use.
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	The California Retail Pharmacy license and DEA license are on display in waiting area. The non-resident licenses are kept in a binder in the office. The CA license is currently on probation, and a sign is posted in the waiting area.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	1/10/2020. CA BOP inspects every three months due to the probationary status of the pharmacy license.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	N/A	No deficiencies on last report.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	Yes	The pharmacy and the PIC are on probation due to improper shipment of compounded product in 2015, which resulted in adulteration of the compounded product. The terms of probation include quarterly inspections by CA BOP. The Probation from the Stipulated Settlement and Order will end on 3/11/2022.
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	The pharmacy and the PIC are on probation due to improper shipment of compounded product in 2015, which resulted in adulteration of the compounded product. The terms of probation include quarterly inspections by CA BOP. The Probation from the Stipulated Settlement and Order will end on 3/11/2022.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	Yes	10/4/18-10/11/18. FDA observed that they did not use USP grade purified water as a component in their non-sterile compounds. The pharmacy corrected the observation by switching to Sterile Water for Irrigation, and notified the FDA that they planned to install a water filtration system capable of producing USP grade purified water. The FDA requested additional information concerning the testing of water from the filtration system and about their cleaning procedures. The pharmacy responded and provided their cleaning P&P. All correspondence is found in Attachment #2 - FDA Inspection and Response.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	UCAP via NABP. Accreditation valid 11/19/2018-11/19/2020.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	N/A	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are maintained onsite for 3 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Records are maintained onsite for 3 years.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are maintained in hard copy onsite for 3 years and electronically indefinitely.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	They are maintained in hard copy onsite for 3 years and electronically indefinitely.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Digital RX does not allow prescriptions to be deleted. The pharmacy system is backed up daily to a Digital RX server.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Per the PIC, they follow the most stringent laws/regulation per their P&P.

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	All licenses are posted. The PIC's license is on probation until 3/11/2022.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The PIC checks all licenses once yearly on the CA BOP website.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	CA requires 1:1 and if a 2 RPh are present, the ratio can increase to 3:2. On the day of the inspection, the ratio was 3:3.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT provides video and motion detection for security.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	None on site.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Pharmacist would remain on site until drug products could be secured.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction on site.

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Prescription products are sent for destruction to Medcycle Systems in Los Angeles, CA.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Hazardous waste is picked up by Medcycle Systems when bins are full.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Pharmacy is primarily considered as a closed-door facility. Occasionally, there are a few walk-ins. There is a separate counseling area for patients.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Unknown	The temperature is thermostat controlled with an excursion range of 65-77°F. The temperature in compounding room 68.9°F, the storage room was 72.6°F and the shipping room was 73.6°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	The temperature is monitoring using LaCrosse technologies devices. If the excursion range is exceeded, an email alert is sent to PIC. This replaced texts alerts which were not reliable.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	PIC would contact the manufacturer to determine if product has been compromised.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The temperature is monitoring using LaCrosse technologies devices. The excursion range is 36-46°F. If the excursion range is exceeded, an email alert is sent to PIC. This replaced texts alerts which were not reliable. Records kept per rules/regulations.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	The temperature was 40.8°F.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen product, used for ice blocks.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	No frozen product, used for ice blocks.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Product requiring refrigeration would be placed in ice chest with ice blocks.

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	They are contracted with Mario Ramos, Inc. - local HVAC company.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	They would quarantine the product and contact the manufacturer to determine if product has been compromised.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The PIC requires that wholesalers have VAWD accreditation, and any API must be USP grade. Additionally, the PIC checks the CA BOP website to ensure they are licensed in CA.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Bellcogenerics, an Amerisource Bergen Drug Corporation division.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Unknown	Per the PIC, they rely on the wholesaler.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Unknown	Per the PIC, they rely on the wholesaler.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Unknown	Per the PIC, they rely on the wholesaler.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Unknown	Per the PIC, they rely on the wholesaler.

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Facility Name: Algunas Inc dba Woodland Hills Pharmacy
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		Finding	Notes
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	They would quarantine the product and contact the manufacturer.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	The PIC stated they do not look at the transaction data.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	They have a quarantine area.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	There are currently no CIIs in stock. They keep the unexecuted DEA 222 forms in an unlocked drawer in the compounding area. The PIC and 1 RPh has authority to sign the 222s.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	No	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	None received in past 2 years.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	No	Two recent invoices were not signed or dated.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory of APIs maintained in PK software. Very small inventory of manufactured prescription products, none of which are controlled substances.

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		Finding	Notes
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	If it occurred, it would be reported to law enforcement and the board of pharmacy. Two years ago two employees were discharged for credit card theft. They were reported to local law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	No CIIs in inventory.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	No CIIs in inventory.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Last inventory on 1/30/19. Inventory conducted every 2 years.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	N/A	None to date.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Product is checked weekly, and outdated, damaged or recalled products are placed immediately in a Medcycle Systems receptacle for destruction/ include OTC products if any
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Weekly.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	

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		Finding	Notes
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	The prescriptions dispensed are mailed to customers and returns not accepted. The PIC did not recall any returns from prescriptions that were picked up at the pharmacy (only 1-2 per week).
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	The Pharmacy Services representatives, who are licensed as pharmacy technicians, enter the patient profile data. Data is updated when new information is received. A pharmacist calls and counsels all patients receiving new prescriptions, and she updates any information as necessary.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	No veterinary prescriptions.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Most prescriptions are received directly from the provider. If the patient supplies the prescription, they call the prescriber to verify. They dispense very few controlled substances.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	They would call the provider. If it was fraudulent they would not dispense and would contact proper authorities.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	They compare the address of the patient and the prescriber. Many patient specific compounded dental preparations are sent directly to the dentist for in office procedures.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	They can accept both via Surescripts.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	They utilize a tech check tech process prior to compounding, and a pharmacist provides the final check.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	A DUR is conducted upon prescription input and again upon patient consultation.

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		Finding	Notes
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	No	The patient profile does not include other medications taken or disease states.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	They have USP 795 and 800, Merck index, Trissels, Pharmacy Calculations, and Pharmaceutical Excipients.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	They submit daily to CA through the Digital RX software. They do not ship controls to other states, and have waivers for PMP submission.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	All DUR overrides/bypasses are documented electronically. Only pharmacists can override a DUR.
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	Yes	First Data Bank.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	When the patient is counseled, any pertinent information would be entered into the electronic notes in patient profile.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	No veterinary prescriptions.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	All prescriptions are verified by a pharmacist. The pharmacist initials the hardcopy of the prescription and the prescription label.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labeled per CA and Federal law.

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		Finding	Notes
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination.* *Record name/brand of pharmacy computer system used.*	Yes	Digital RX. Levels of access are assigned by job type, and overseen by IT.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	The label or the whole vial is placed in a bin and shredded by Shred-It.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	They ship all product in U-line boxes.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Finding	Notes
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	If a patient comes to the pharmacy for pick up, they are counseled by a pharmacist (very rare - 1-2 times per week).
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	Not unless requested by patient.
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Technician.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	No prescriptions are delivered.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	One pharmacist monitors all new prescriptions that are mailed via a shared Google Document with the shipping department. She tracks each shipment and calls the patient prior to delivery to provide counseling. They also provide written information.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Most prescriptions are compounded, so PPIs are not required or available. They have developed some information sheets for certain compounded preparations.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	N/A	No products with MedGuides are dispensed.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	No products requiring REMS are dispensed.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	It is documented in the patient profile.

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		Finding	Notes
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state.* *Describe how (such as posted contact information and hours of operation).*	No	Patients may leave a voice mail and receive a call when the pharmacy is open.
85.00	Are processes in place to handle a drug recall?	Yes	The lot number of the compounded product is recorded in Digital RX, to assist in recalls.
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.01	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	PIC.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	They are maintained in hard copy in a notebook.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	

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		Finding	Notes
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	It is documented immediately on hard copy, and maintained in a notebook.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*	Yes	PIC analyzes with each event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	No	Per PIC, quality meetings are held once per year. No quality meeting was held in 2019, last meeting documented was 5/23/18. Per the PIC, "we are a little bit behind".
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	Inspector reviewed Quality meeting minutes from 2017 and 2018.
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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		Finding	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	No	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	The PIC conducts quality self audits quarterly or more often if needed.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	No	Patient profiles contain allergy information. They do not include disease states or other prescriptions taken by the patient that are dispensed by other pharmacies.
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes	Very few, approximately 1-2 per week.
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	No	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	No	
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	No	
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	No	
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	No	
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*	No	
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*	N/A	
2.06	If yes, are any of these controlled substances? *List compounds provided.*	N/A	

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		Finding	Notes
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*	Yes	Capsules, suspensions, solutions, troche.
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*	Yes	Gels, creams, ointments, nasal sprays, suppositories.
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*	No	
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*	No	
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	Yes	5%
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	Yes	Nature thyroid has been on Drug Shortage list. The PIC checks FDA website and ASHP drug shortage list to verify shortage.
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	Yes	It would be quarantined.
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	Yes	5%

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	60%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	Yes	35%
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	15%
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	They do all compounding of hazardous drugs in a new USP 800 compliant room.
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*	Yes	1%
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*	Yes	Medisca, PCCA, Spectrum, Fagron, Letco, Humco, Damerica (Attix), B&B
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	The PIC checks this as part of the vetting process for vendors.

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		Finding	Notes
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*	Yes	Inspector observed Grapeseed extract from Bulk Supplements in the compounding area. See Attachment #3 for invoice from Amazon.
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*	Yes	It is tracked in the PK software.
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	Yes	Capsule weights and pH are checked in-house.
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	Yes	ARL tests for potency over time to extend BUDs.
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*		Ohaus Adventurer x 3.
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*	Yes	Calibrated daily with calibration weight. Reviewed daily log of calibration checks posted in the compounding room.
19.03	Describe the pharmacist checks for the measurement of each ingredient		The weight is recorded on a printout, and a pharmacist is called into the compounding room to check the weights and initial the compounding record.
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	No	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	Yes	
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	

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		Finding	Notes
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	No	
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**5**	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Unknown	Located Grape Seed Extract Powder distributed by Bulk Supplements (purchased through Amazon - Attachment #3) in the compounding room. See Picture #1.
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	COAs are stored electronically and available for review.
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Unknown	Unable to determine if Grape Seed Extract Powder distributed by Bulk Supplements meets this criteria.
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	Non-Compliant	See Picture #2- photo of Trichloroacetic Acid from Spectrum Chemicals - labeled "not for food or drug use". Attachment #4 is a compounding record where this product is used for a skin peel applied by a physician.
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	N/A	No veterinary products are compounded.

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		Finding	Notes
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	Compliant	
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	Compliant	
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	Non-Compliant	They assign the expiration date of the original container.
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	They use sterile water for irrigation for all compounding and rinsing.
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	Unknown	Unable to determine if Grape Seed Extract Powder distributed by Bulk Supplements meets this criteria.
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	They have a reference: Handbook of Pharmaceutical Excipients.
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.	N/A	No veterinary products are compounded.
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	N/A	

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		Finding	Notes
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**3**	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Unknown	Topical hormone preparations are assigned a 180 day BUD based upon a Humco study that validates the BHRT base for 180 days, however, the various concentrations of hormones added do not have stability testing.
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	Non-Compliant	The pharmacy has conducted stability studies through ARL labs on most of their compounded products, however some topical products (Lidocaine Nasal Spray and Daily Complexion Pads) have been assigned an extended BUD without supporting testing.
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Non-Compliant	Lidocaine Nasal Spray and Daily Complexion Pads are assigned a 90 day BUD without stability testing.

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		Finding	Notes
Environment			
	Total Non-Compliant (Includes Unknowns)	**2**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	They have a separate room for compounding hazardous medications. The room was certified last on 1/20/2020.
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Compliant	They have a CVE that is vented to the outside.
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	Compliant	The CVE was last certified on 1/20/2020 by Clean Room Services of Canoga Park, CA.
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	N/A	
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	Compounding technicians were garbed in hair bonnet, N-95 mask, gown, booties, and gloves.
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*	Compliant	Per the PIC, they currently rinse all equipment and utensils with sterile water for irrigation. They have installed a water distiller, and currently working with ARL to validate the water purity.

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		Finding	Notes
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Non-Compliant	The temperature is thermostat controlled with an excursion range of 65-77°F. The temperature in compounding room 68.9°F. A review of the temperature logs did not detail any temperatures below 68°F.
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	The temperature is monitoring using LaCrosse technologies devices. If the excursion range is exceeded, an email alert is sent to PIC. This replaced texts alerts which were not reliable. Temperature records are maintained electronically.
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Non-Compliant	The temperature is thermostat controlled with an excursion range of 65-77°F. The temperature in the storage room was 72.6°F and the shipping room was 73.6°F. A review of the temperature logs did not detail any temperatures below 68°F.
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	The temperature is monitoring using LaCrosse technologies devices. If the excursion range is exceeded, an email alert is sent to PIC. This replaced texts alerts which were not reliable. Temperature records are maintained electronically.
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.	Compliant	The excursion range for humidity is 35-60%. Humidity on the day of inspection was 49%.
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	The humidity is monitored using LaCrosse technologies devices. If the excursion range is exceeded, an email alert is sent to PIC. Humidity records are maintained electronically.
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	They would quarantine and contact the manufacturer.
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	Compliant	The excursion range for humidity is 35-60%. Humidity on the day of inspection in the storage room and shipping room was 49%.

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		Finding	Notes
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	The humidity is monitored using LaCrosse technologies devices. If the excursion range is exceeded, an email alert is sent to PIC. Humidity records are maintained electronically.
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	They would quarantine and contact the manufacturer.
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	Hazardous waste is picked up on request by Medcycle Systems.
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	

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		Finding	Notes
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	Reviewed annual training files for the compounding technicians.
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	N/A	
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*	Compliant	Scales/balances and pH meter are calibrated annually by Watson Brothers. The scales/balances are calibrated daily with a calibration weight, and a written log is maintained of this calibration.
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Compliant	Powder hoods are certified every 6 months by Clean Room Services from Canoga Park, CA.
58.01	Hood filters are checked regularly and replaced when necessary.	Compliant	
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*	Compliant	
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	All HD drugs are stored and compounded in negative pressure HD room. They do not compound with beta lactams.

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		Finding	Notes
Documentation			
	Total Non-Compliant (Includes Unknowns)	5	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Non-Compliant	Not all extended BUDs have been validated by stability testing.
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	
61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Compliant	
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Non-Compliant	Not all extended BUDs have been validated by stability testing.
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	Compliant	
61.12	Description of the finished preparation	Non-Compliant	Not all MFR include a description of the final product.
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	

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		Finding	Notes
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Non-Compliant	Not all compounding records include a description of the final preparation.
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	Non-Compliant	A duplicate label is not included with the compounding record.
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
	Compounding Procedures		
	Total Non-Compliant (Includes Unknowns)	1	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Compliant	
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	Compounding technicians were garbed in hair bonnet, N-95 mask, gown, booties, and gloves.
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	Compounding technicians were garbed in hair bonnet, N-95 mask, gown, booties, and gloves.
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	Compounding technicians were garbed in hair bonnet, N-95 mask, gown, booties, and gloves.
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	The compounding technician weighs each of the components, and prints out a paper log recording the weights. The pharmacist is called to verify the components and their weights prior to the components being combined into a final product.
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	Non-Compliant	Inspector reviewed multiple compounding logs and noted the paper log of the weights with the initials of the technician and the pharmacist. Missing description of final product.
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment.* ***Compounding MUST be observed****, if compounding is not being performed at the time of survey, mark as "Non-Compliant".*	Compliant	Observed compounding of Naltrexone HCl (LDN) 3 mg capsules #100 and addition of Crème de Menthe flavoring and green color to a previously prepared dental compound of Lidocaine 12.5%/Tetracaine 12.5%/Prilocaine 3%, with subsequent packaging into individual use containers of 30mL.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "* ***Denial of Authorization*** *" form. List individual who signs the Denial of Authorization*		N/A
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**2**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Non-Compliant	Not all MFR include a description of the final product.
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	Non-Compliant	Not all extended BUDs have been validated by stability testing.
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	Compliant	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	Compliant	
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	

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Verified Pharmacy Program® Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Algunas Inc dba Woodland Hills Pharmacy
e-Profile ID: 821758
Inspection Date: 03/12/2020

		Finding	Notes
80.03	Labeling contains storage and handling information.	Compliant	
80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.	Compliant	
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Compliant	
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review
EMT	Emergency medical technician

EPA	Environmental Protection Agency
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement
QRE	Quality Related Event
RAM	Radioactive Material
RCRA	Resource Conservation and Recovery Act

REMS	Risk evaluation mitigation strategy
RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

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Explanation of Discipline by State Boards of Pharmacy

The following have occurred regarding the licenses of Woodland Hills Pharmacy and Steven A. Levin RPh, its Pharmacist-in-Charge:

a. In 2015, the Alabama Board of Pharmacy denied the application of Steven A. Levin for licensure as a pharmacist based on a) January 4, 2012 discipline by the California Board of Pharmacy for failure to maintain proper records b) the March 6, 2012 discipline by the California Board of Pharmacy for allowing a clerk to perform unauthorized duties and failing to follow requirements for compounded products c) a conviction on May 10, 1983 for sale of marijuana.

b. Oregon Board of Pharmacy consent order regarding the pharmacist on April 22, 2015 imposing a fine and completion of continuing education for failure to disclose the 1983 conviction sale of marijuana.

c. South Carolina State Board of Pharmacy denial of pharmacy license on September 18, 2015 for failure to perform salt to base conversions not consistent with current pharmacy compounding standards and not having customized policy and procedures.

d. Texas Board of Pharmacy on January 9, 2017 imposed fine for failure to report the 2015 order from the Alabama Board, the 2015 Order from the Oregon Board and the 2015 order from the South Carolina Board on the pharmacy's renewal application.

e. Nebraska Department of Health and Human Services on February 7, 2017, issued an order on agreed settlement imposing a fine on the pharmacist for failure to disclose the 2015 order from the Alabama Board, the 2015 Order from the Oregon Board and the 2015 order from the South Carolina Board, the 2016 order from the Louisiana Board on the 2016 application for reinstatement of the pharmacist license.

f. The California Board of Pharmacy issued a Stipulated Order on February 9, 2018 against Woodland Hills Pharmacy and its PIC Steven A. Levin effective March 12, 2018 placing the pharmacy and pharmacist on four years of probation subject to notice, education and other requirements. The violations were for the sale of Amphotericin B and for failure to properly store and deliver Amphotericin B.

g. The Nevada Board of Pharmacy, on April 26, 2018, renewed the pharmacist license registration of Steven Levin and placed him on probation on the following conditions: 1. Comply with the conditions imposed by the California Board of Pharmacy 2) notice the Board of any change in license status in California 3) not practice in Nevada without prior authorization of the Executive Secretary of the Board.

h. Louisiana Board of Pharmacy Consent Agreement dated May 23, 2018 imposing probation that the pharmacy abides by conditions imposed by California Board of Pharmacy.

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i. Louisiana Board of Pharmacy Consent Agreement dated May 23, 2018 imposing probation that the pharmacist abides by conditions imposed by California Board of Pharmacy.

j. Oregon Board of Pharmacy Consent Order dated October 2, 2018 imposing probation that the pharmacy abides by conditions of probation imposed by California Board of Pharmacy.

k. Oregon Board of Pharmacy Consent Order dated October 2, 2018 imposing probation that the pharmacist abides by the conditions imposed by the California Board of Pharmacy.

l. Virginia Board of Pharmacy --Mandatory suspension under Virginia law on July 27, 2018, without a hearing, based on California order.

m. Texas Board of Pharmacy issued a Stipulated Order on December 6, 2018 Discipline imposing probation concurrent with California Order entered 11/3/2017. The alleged violations were based on out of state Orders ie California -compounding errors; Louisiana and Virginia – subject to disciplinary action by another Board:

n. Colorado Board of Pharmacy issued a Letter of Admonition on January 2, 2019 because the Pharmacy sold adulterated dangerous drugs that did not conform to standards and tests as to quality and strength.

o. Pennsylvania Board of Pharmacy has ordered, on April 19, 2019, that when the pharmacy license is issued it will be placed on Probation for an indefinite period of time, until such time as each and every one of Applicant's pharmacy permits, registrations, licenses, or any other authorizations to practice, in every jurisdiction in which Applicant possesses such authorizations, shall be active and unencumbered. The license issued on July 5, 2019 and status is Active-On Probation.

p. Illinois Board of Pharmacy, on June 5, 2019 issued a Consent Order imposing indefinite probation and that the pharmacy abides by all terms and conditions imposed by California Board of Pharmacy.

q. Michigan Board of Pharmacy, on October 9, 2019 ordered a $500 fine to be paid by the pharmacist under the Public health Code MCL 333.1101 et seq because of the violation of the Public Health Code by virtue of the California disciplinary action.

r. Wisconsin Division of Legal Services and Compliance, on October 341, 2019 issued a letter regarding the pharmacy that upon completion of its investigation of the self-complaint, it closed the case for prosecutorial discretion based on the California Board's addressing of the conduct and further action in Wisconsin was unnecessary.

s. Maryland Board of Pharmacy, on Nov 8, 2019, issued its order against the pharmacist under the Maryland Pharmacy Act charging certain violations of Maryland Code Annotated Health Occupations §§12-101 et seq imposing probation reciprocal to California and further ordering that various inspection reports be furnished to the Board on a regular basis.

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t. Arizona Board of Pharmacy, on November 20, 2019, issued an Advisory Letter granting renewal license and permit and the violation was a minor or technical violation that was not of sufficient merit to warrant disciplinary action. It is noted that the vast majority of the adulterated medication was dispensed to Arizona patients.

Note on California Order

The pharmacy would like to note that most states have not revoked the pharmacy permits of Woodland Hills Pharmacy or the pharmacist licenses based on the California Order. Instead, most states have instituted reciprocal probation. Further, it is noted that Woodland Hills Pharmacy and Steven Levin have not contested any of the imposed discipline that has resulted from the probation in the pharmacy's home state and have entered into stipulations and consent agreements without the necessity of any contested hearings. The pharmacy is complying with all terms of the probation.

Corrective Actions Related to Discipline in California

Following the California Board of Pharmacy Inspection in 2015, which was what resulted in the probation in 2018, Woodland Hills Pharmacy immediately undertook actions to correct deficiencies. The pharmacy made numerous changes to its compounding practice including:

1. The pharmacy changed policies and procedures related to storage and shipping. Testing was performed using a sensor to determine whether the temperature range of the medication reached certain extremes during shipment. The results came back negative for both high and low temperature extremes.

2. All forms of amphotericin are shipped overnight with cold packs. This policy has been in place since the California Board of Pharmacy inspection in 2015. No amphotericin has been shipped improperly since then. We remain dedicated to ensuring all medications are properly packaged to maintain drug integrity.

3. We clarified our policy on beyond use dating. We adhere to USP 795 recommendations for water-containing topical/dermal or mucosal formulations, unless further testing proves otherwise.

Because of changes made following the California Board of Pharmacy inspection, the pharmacy is no longer in violation of state regulations and has not been for some time. The pharmacy does not ship amphotericin without cold packs. The pharmacy uses temperature sensors in drug storage, compounding, and shipping areas. All temperature excursions are immediately reported to the pharmacist-in-charge. All drugs are stored at the proper temperature and checks are performed before they are dispensed.

In addition, the pharmacy is now NABP accredited. The pharmacy would not have been able to achieve NABP accreditation or maintain its license in multiple states if it had not made corrections that improved the quality of its compounding activities.

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Voluntary VPP Inspection

Woodland Hills Pharmacy voluntarily requested to have NABP Verified Pharmacy Program (VPP) inspections conducted. The inspection helped the pharmacy further improve its policies and procedures. In addition, the pharmacy fulfilled the requirements for NABP accreditation based on the results of the VPP inspection.

Comments

The pharmacy and the PIC have met all requirements of the California probation and reciprocal probation in other states. The pharmacy's home state of California has not revoked its permit based on the adulteration of amphotericin B, which was the cause of the probation order. It is further noted that the majority of state boards did not revoke the pharmacy permits or pharmacist licenses and instead instituted reciprocal probation to mirror the California order. Woodland Hills Pharmacy has used the observations of inspectors as guidance in improving our pharmacy and the quality of our products, so that we are now meeting or exceeding all regulations and standards. The pharmacy respectfully requests that the Iowa Board of Pharmacy consider this when making their determination about the approval of our application.

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

February 9, 2018

CERTIFIED MAIL

Steven Levin, President
Woodland Hills Pharmacy
20631 Ventura Blvd, Suite 305
Woodland Hills, CA 91364

RE: Administrative Case No. 5704
Woodland Hills Pharmacy, PHY 50815
Steven A. Levin, RPH 46443

Dear Mr. Levin:

Attached is the Decision and Order of the Board of Pharmacy (Board) regarding the above-referenced matter. Your attention is directed to pages 4 through 18 of the Stipulated Settlement and Disciplinary Order.

Effective at 5:00 p.m. on March 12, 2018, Pharmacy Permit No. PHY 50815 issued to Woodland Hills Pharmacy is revoked; however, said revocation is stayed, and the pharmacy license is placed on probation for four (4) years, from March 12, 2018 through March 21, 2022, inclusive.

Effective at 5:00 p.m. on March 12, 2018, Pharmacist License No. RPH 46443 issued to Steven A. Levin is revoked; however, said revocation is stayed, and the pharmacy license is placed on probation for four (4) years, from March 12, 2018 through March 21, 2022, inclusive.

You will be scheduled to appear before representatives of the Board. The purpose of your appearance is to explain to you the terms and conditions of your probation and your responsibilities as a probationer. The Board will contact you regarding the date of your appearance.

Upon successful completion of the four-year probation period, or extension thereof, the licenses will be fully restored. However, upon violation or failure to comply with any of the terms and conditions of this stay, the Board may, after notice and opportunity to be heard is given to you, vacate the stay and re-impose the revocation, or take other action as it deems appropriate.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Jane Russell, Enforcement Analyst, at (916) 574-7941.

Sincerely,

VIRGINIA K. HEROLD
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

Enclosure

cc: Gillian E. Friedman, DAG
Noah Jussim, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 5704
Woodland Hills Pharmacy, PHY 50815
Steven A. Levin, RPH 46443

I am over 18 years of age, and not a party to the within cause; my business address is 1625 N. Market Blvd, Suite N 219, Sacramento, California 95834. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed as follows:

NAME	CERTIFIED NO.
Steven Levin, President Woodland Hills Pharmacy 20631 Ventura Blvd, Suite 305 Woodland Hills, CA 91364	7017 0530 0001 1515 6994
Steven A. Levin 22349 Algunas Road Woodland Hills, CA 91364	7017 0530 0001 1515 7007
Noah Jussim, Esq. Hinshaw 7 Culbertson LLP 633 West 5th Street, 47th Floor Los Angeles, CA 90071	7017 0530 0001 1515 7014

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 9, 2018, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 9, 2018, at Sacramento, California.

Susan Cappello

Susan Cappello, Enforcement Manager

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ALGUNAS INC. DBA WOODLAND HILLS PHARMACY, STEVEN A. LEVIN PRESIDENT** 20631 Ventura Blvd., Ste. 305 Woodland Hills, CA 91364 STEVEN A. LEVIN, Pharmacist-in-Charge **Original Permit No. PHY 50815** **STEVEN A. LEVIN** 22349 Algunas Road Woodland Hills, CA 91364 **Original Pharmacist License No. RPH 46443** Respondents.	Case No. 5704 OAH No. 2017050144

DECISION AND ORDER

The attached Stipulated Settlement of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 12, 2018.

It is so ORDERED on February 9, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

XAVIER BECERRA
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General
GILLIAN E. FRIEDMAN
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300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6294
Facsimile: (213) 897-2804
E-mail: Gillian.Friedman@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **ALGUNAS INC. DBA WOODLAND HILLS PHARMACY, STEVEN A. LEVIN PRESIDENT** 20631 Ventura Blvd., Ste. 305 Woodland Hills, CA 91364 STEVEN A. LEVIN, Pharmacist-in-Charge **Original Permit No. PHY 50815** **STEVEN A. LEVIN** 22349 Algunas Road Woodland Hills, CA 91364 **Original Pharmacist License No. RPH 46443** Respondents.	Case No. 5704 OAH No. 2017050144 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Gillian E. Friedman, Deputy Attorney General.

2. Respondent Algunas Inc dba Woodland Hills Pharmacy with Steven A. Levin as President and Respondent Steven A. Levin Pharmacist in Charge (Respondents) are represented in this proceeding by attorney Noah Jussim, whose address is: Hinshaw & Culbertson LLP, 633 West 5th Street, 47th Floor, Los Angeles, California, 90071, Tel: 213-614-7326.

3. On or about February 1, 2012, the Board of Pharmacy issued Original Permit Number PHY 50815 to Algunas Inc., doing business as Woodland Hills Pharmacy, with Steven A. Levin as the President, Pharmacist-in-Charge, and 100% shareholder (Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2018, unless renewed.

4. On or about August 13, 1993, the Board of Pharmacy issued Original Pharmacist License Number RPH 46443 to Steven A. Levin (Respondent Levin). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2018, unless renewed.

JURISDICTION

5. Accusation No. 5704 was filed before the Board, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on February 23, 2017. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 5704 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondents have carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5704. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

9. Respondents admit the truth of each and every charge and allegation in Accusation No. 5704.

10. Respondents agree that Original Permit Number PHY 50815 and Original Pharmacist License Number RPH 46443 are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

11. Respondents further agree that they are subject to additional discipline by the Board pursuant to Business and Professions Code section 4301 subdivision (n) due to out of state discipline. The circumstances are that on May 2, 2017, Respondents entered into an Agreed Board Order #F-16-036 with the Texas State Board of Pharmacy whereby Respondents were required to pay an administrative penalty in the sum of $1,000 for failing to disclose in their renewal of pharmacy license application the following: (a) the denial of Respondent Levin's reciprocity application for licensure as a pharmacist by the Alabama State Board of Pharmacy on January 25, 2015 based upon discipline by the California Board and a 1983 conviction for transportation/ sale of marijuana in Long Beach, California; (b) a Consent Order with the Oregon State Board of Pharmacy on April 28, 2015 following Respondent Levin's application for licensure as a Pharmacist. The Consent Order required Respondent Levin to pay a fine and complete three hours of continuing education due to his arrest for the transport/sale of marijuana; and (c) the denial of Respondent Pharmacy's nonresident pharmacy permit on September 3, 2015 with the South Carolina State Board of Pharmacy due to testimony received by that board from Respondent Levin relating to the compounding of pain medications.

12. Respondents admit the truth of each and every charge and allegation set forth in paragraph 11 above.

SL

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER AGAINST ALGUNAS INC

DBA WOODLAND HILLS PHARMACY

IT IS HEREBY ORDERED that Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy with Steven A. Levin as the President, Pharmacist-in-Charge, and 100% shareholder (Respondent Pharmacy) is revoked. However, the revocation is stayed and Respondent Pharmacy is placed on probation for four (4) years on the

following terms and conditions.

1. **Obey All Laws**

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- ☐ an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- ☐ a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- ☐ a conviction of any crime
- ☐ discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacy Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the

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board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, respondent owner shall jointly and severally with Respondent Levin be responsible to pay to the Board its costs of investigation and prosecution in the amount of $7870.50. Costs may be paid on a payment plan approved in writing by the board. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

6. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. **Status of License**

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any

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time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

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9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. **Posted Notice of Probation**

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation

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of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. **Violation of Probation**

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. **Consultant for Owner or Pharmacist-In-Charge**

If during the period of probation Respondent Levin serves as a pharmacist-in-charge, Respondent Pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. The Consultant must have compounding experience. Respondent shall not be a pharmacist-in-charge at more than one pharmacy. Failure to timely retain, seek approval of, or

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ensure timely reporting by the consultant shall be considered a violation of probation.

During the period of probation, the board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations.

15. **Remedial Education**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding for all pharmacy staff involved in compounding. The program of remedial education shall consist of at least six (6) hours and shall be completed within six months of probation at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require pharmacy staff of the respondent, at respondent pharmacy's expense to take an approved examination to test the respondent's knowledge of the course. If the pharmacy staff does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

DISCIPLINARY ORDER AGAINST PHARMACIST STEVEN A. LEVIN

IT IS HEREBY ORDERED that Original Pharmacist License Number RPH 46443 to Steven A. Levin (Respondent Levin) is revoked. However, the revocation is stayed and Respondent Levin is placed on probation for four (4) years on the following terms and conditions.

16. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

17. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

18. **Interview with the Board**

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

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19. **Cooperate with Board Staff**

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

20. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

21. **Notice to Employers**

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5704 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5704, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5704 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they has read the decision in case number 5704

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and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

22. **No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant**

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board other than Algunas Inc., doing business as Woodland Hills Pharmacy nor serve as a consultant, unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

23. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Levin shall pay to the board its costs of investigation and prosecution in the amount of $7,870.50. Respondent Levin shall be jointly and severally responsible for payment of costs with Respondent Pharmacy. Costs may be paid on a payment plan approved in writing by the board.

Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

24. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as

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directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

25. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

26. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish their pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

27. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new

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employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

28. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

29. **Violation of Probation**

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until

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all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

30. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

31. **Restricted Practice**

Respondent shall be restricted from the practice of pharmacy compounding until he has satisfactorily completed a Board approved remedial compounding course (Live attendance required course) and must do so within one year of the effective date. Respondent must complete at least six (6) hours of compounding related courses prior to resuming compounding activities. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

32. **Community Services Program**

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least thirty-two (32) hours per year within one year of the effective date. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or

comply with the program shall be considered a violation of probation.

33. **Remedial Education**

Within sixty (60), days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding. The program of remedial education shall consist of at least six (6) hours, which shall be completed yearly at respondent's own expense. At least 50% of the training must be in person training. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at their own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Respondent shall be restricted from the practice of compounding until the initial six (6) hours of remedial education program has been successfully completed.

34. **No Ownership of Licensed Premises**

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

35. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah Jussim, Esq., Hinshaw & Culbertson LLP. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11/3/17

STEVEN A. LEVIN,
President & Pharmacist in Charge
ALGUNAS INC DBA WOODLAND HILLS PHARMACY, *Respondent*

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah Jussim, Esq., Hinshaw & Culbertson LLP. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11/3/17

STEVEN A. LEVIN
Respondent

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I have read and fully discussed with Respondents Algunas Inc dba Woodland Hills Pharmacy with Steven A. Levin as President, Pharmacist in Charge and Steven A. Levin, Pharmacist the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 11/3/17

Noah Jussim, Esq.
Hinshaw & Culbertson LLP
Attorneys for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 11/3/17

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General

GILLIAN E. FRIEDMAN
Deputy Attorney General
Attorneys for Complainant

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California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 1/10/2020 Inspector: Simin Samari

Firm: WOODLAND HILLS PHARMACY Phone: (855) 876-3060

Address: 20631 VENTURA BLVD STE 305 City: WOODLAND HILLS Zip: 91364

Ownership: CORPORATION

Permit #: PHY50815 Permit Exp: 2/1/2021 DEA#: FW3071507 DEA Exp: 5/31/2021

Date of Self Assessment Form: 9/30/2019 Other Permit #: N/A Date of DEA Inventory: 1/30/2019

Hours M-F: 8AM-4:30PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC STEVEN A LEVIN RPH46443 Administrator

RPH Consultant

Staff RPH Name:	License #:
LAUREN L FALLIERAS	RPH65381
AMIT P SULE	RPH54528

Staff Name:	License #:
EDNA C BETETA (COMP)	TCH159883
ERICK G MURCIA (COMP)	TCH125637
JENNIFER B STEWART (DAT	TCH165870
JODY LEVIN (OWNER/FINA	CLERK
MARTIN LOISELLE (MARKE	CLERK
MASSIEL FIGUEROA (DATA	TCH151376
MICHELLE M MORENO (DA	TCH43442
RAUN LAUDERDALE (DATA	CLERK
REINA MAGANA MEZA (CO	TCH135811

Inspector Remarks:

Here to visit the pharmacy.
Reviewed and discussed the following with PIC Levin and RPH Sule: orders compounded pursuant to a prescription order per patient and mailed to prescriber's office for dispensing to the patient as part of patient treatment package or office use for that patient, patient consultation/drug monographs, auxiliary labels, staff's access to compounding references and water for compounding/rinsing utensils.
Checked the inventory for any non-USP-NF active ingredients.
Reviewed: new technician, Edna Beteta's training records.
Reviewed: worksheet for ketotifen 0.5mg capsule
Reviewed: end product testing records
Reviewed: consultant Oscar Tello's 10/30/19 and 11/27/19 reports.

CI 2018 83105: PIC Levin and RPH Sule stated all new orders are followed up by RPH Fallieras. Once patient receives the medications, she contacts the patient, if available, she consults them on the medication and answers any questions the patient may have. PIC provided a spread sheet indicating RPH Fallieras' notes.
The pharmacy generates receipt that includes information to contact the pharmacy's number for consultation. PIC states the number is Toll free.

PIC Levin works every day at the pharmacy.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Board's costs are all paid off.
Terms 15, 31, 32, 33 and 35 are completed.
PIC Levin states he does not have any new ownership or any involvement with any new ownerships with the BOP.

***As of 1/1/20 compounding pharmacies need to comply with current USP chapters. Make sure to train staff on these chapters.
***Suggest more frequent end-product testing.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____
Pharmacist (print) Steven Levin

Inspector (sign) _____
Inspector (print) _____

Owner(sign) _____
Owner(print) Steven Levin

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

OFFICIAL RECEIPT

January 10, 2020

Receipt Number: 290555

Firm: WOODLAND HILLS PHARMACY

Address: 20631 VENTURA BLVD STE 305, WOODLAND HILLS CA 91364

Permit #: PHY50815

Phone: (855) 876-3060

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Qty	Units	Description
1	Page(s)	Progesterone 50mg Rx list dated 1/1/19 to 1/10/20
1	Page(s)	EDTA/Colloidal Silver Rx list dated 1/1/19 to 1/10/20
1	Page(s)	Counseling Record & Third Party Log
1	Ea	Rx label for Rx 172209 dated 1/9/20
1	Page(s)	Spread sheet indicating delivery and pt consultation status.

Voluntarily Released for Investigation

Receipt acknowledged by: _____ PIC
Title

Inspector: _____

PHARMACOM LLC
A Consulting Company

Subject: Woodland Hills Pharmacy
Date of Visit: May 21, 2020

To: Steve Levin, RPH
Autumn Ammann, Probation Analyst

RE: Case Number #5704
Pharmacy #50815
Pharmacist #46443

Steve Levin was not present during my visit; pharmacist Amit was on duty during the visit. The following are posted in the lobby/waiting area: pharmacy on probation, Ask Your Pharmacist poster, translation information, and pharmacy, pharmacist, and technician licenses. The pharmacy is still continuing to operate with limited hours of operation. All licenses were verified active on BOP website, but current licenses need to be updated in the pharmacy.

No food or drink was found in the refrigerator. Temperature/cleaning logs are current. Hot and cold water is available. Pharmacy compounding area is clean and organized. No expired bulk chemicals found in the compounding areas. Pharmacy areas are restricted to authorized personnel only. They are using the distilled water for washing compounding equipment. Compounding worksheets for the month of May were reviewed. No deficiencies identified.

I reviewed section 503A(b) of the FD&C Act, regarding compounded products that are commercially available:

> A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.
>
> Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.

Sincerely,

Oscar Tello, PharmD

PHARMACOM LLC
A Consulting Company

Pharmacy Inspection Report

Pharmacy Name	Woodland Hills Pharmacy
Date of Visit	05-21-20

License Expiration Date	02/01/21	
Does license expire within 3 months of visit?	Yes____ No___X__	Name: Date:

Pharmacy and Personnel			
	Yes	No	N/A
Pharmacy license visible	X		
Pharmacist and Technician licenses visible	X		
Pharmacy on probation sign posted and visible	X		
Ask Your Pharmacist sign posted and visible	X		
Translation services information sign posted and visible	X		
Personnel identified with badges/titles	X		
Pharmacy access is limited to authorized individuals	X		

Board Requirements			
	Yes	No	N/A
Does pharmacy keep a "State Board of Pharmacy binder"?	X		

Pharmacy and Personnel			
	Yes	No	N/A
Pharmacy Inspection Reports kept on file	X		
Pharmacy self-assessment reports (3 years maintained)	X		
Copies of employee licenses	X		
Master list of pharmacists and technician initials	X		
DEA 222 forms / Power of Attorney	X		
Executed DEA 222 forms/ CSOS receipt reports			X
DEA 106 form for theft and loss (maintained for 3 years)			X
DEA Biannual inventory	X		
DEA Quarterly reconciliation for CII medication	X		
Policies & procedures (pharmacy technicians)	X		
Policies & procedures / quality assurance program for medication errors	X		
Policies & procedures (delivery of meds when pharmacy is closed)	X		
Policies & procedures for Immunizations	X		
Policies & procedures for absence of pharmacist	X		

Protocol/licensee refuses to dispense based on ethical, moral, and/or religious grounds	X		
Purchase invoices separated (non-control, CIII-V, CII)	X		

Compounding Room Inspection Report

Board Requirements			
	Yes	No	N/A
Does pharmacy keep a "State Board of Pharmacy binder"?		X	

Pharmacy and Personnel			
	Yes	No	N/A
Compounding self-assessment reports (3 years maintained)	X		
Policies and Procedures for compounding	X		
Master Formulas	X		
Compounding worksheets	X		
End Product testing results	X		
Competency training and QA records	X		
Hood certification records	X		
Cleaning and equipment maintenance records	X		
Drug Disposal	X		
Hazardous drugs kept separate from non-hazardous drugs	X		

PHARMACOM LLC
A Consulting Company

Subject: Woodland Hills Pharmacy

Date of Visit: April 24, 2020

To: Steve Levin, RPH
Autumn Ammann, Probation Analyst

RE: Case Number #5704
Pharmacy #50815
Pharmacist #46443

Steve Levin was present during my visit. The following are posted in the lobby / waiting area: pharmacy on probation, Ask Your Pharmacist poster, translation information, and pharmacy, pharmacist, and technician licenses. Most of the staff have been furloughed due to COVID-19. Steve is having minimal staff come in for shortened hours of operation until the stay at home order is lifted.

No food or drink was found in the refrigerator. Temperature / cleaning logs are current. Hot and cold water is available. The pharmacy compounding area is clean and organized. No expired bulk chemicals were found in the compounding areas. Pharmacy areas are restricted to authorized personnel only.

Sincerely,

Oscar Tello, PharmD

PHARMACOM LLC
A Consulting Company

PHARMACY INSPECTION REPORT

Pharmacy Name	Woodland Hills Pharmacy
Date of Visit	04/24/2020

License Expiration Date: 02/01/2021		
Does license expire within 3 months of visit?	Yes____ No__X__	Name: Date:

Pharmacy and Personnel			
	Yes	No	N/A
Pharmacy license visible	✓		
Pharmacist and Technician licenses visible	✓		
Pharmacy on probation sign posted and visible	✓		
Ask Your Pharmacist sign posted and visible	✓		
Translation services information sign posted and visible	✓		
Personnel identified with badges/titles	✓		
Pharmacy access is limited to authorized individuals	✓		

Board Requirements			
Does pharmacy keep a "State Board of Pharmacy binder"?	✓		

Sections of Board of Pharmacy Binder			
Pharmacy Inspection Reports	✓		
Pharmacy self-assessment reports (3 years maintained)	✓		
Copies of employee licenses	✓		
Master list of pharmacists and technician initials	✓		
DEA 222 forms / Power of Attorney	✓		
Executed DEA 222 forms/ CSOS receipt reports			✓
DEA 106 form for theft and loss (maintained for 3 years)			✓
DEA Biannual inventory	✓		
DEA Quarterly reconciliation for CII medication	✓		
Policies & procedures (pharmacy technicians)	✓		
Policies & procedures / QA program for medication errors	✓		
Policies & procedures (med delivery when pharmacy is closed)	✓		
Policies & procedures for Immunizations	✓		
Policies & procedures for absence of pharmacist	✓		
Protocol/licensee refuses to dispense based on ethical, moral, and/or religious grounds	✓		
Purchase invoices separated (non-control, CIII-V, CII)	✓		

COMPOUNDING ROOM INSPECTION REPORT

Board Requirements			
	Yes	No	N/A
Does pharmacy keep a "State Board of Pharmacy binder"?		✓	

Pharmacy and Personnel			
	Yes	No	N/A
Compounding self-assessment reports (3 years maintained)	✓		
Policies and Procedures for compounding	✓		
Master Formulas	✓		
Compounding worksheets	✓		
End Product testing results	✓		
Competency training and QA records	✓		
Hood certification records	✓		
Cleaning and equipment maintenance records	✓		
Drug Disposal	✓		
Hazardous drugs kept separate from non-hazardous drugs	✓		

PHARMACOM LLC
A Consulting Company

Subject: Woodland Hills Pharmacy

Date of Visit: March 20, 2020

To: Steve Levin, RPH
Autumn Ammann, Probation Analyst

RE: Case Number #5704
Pharmacy #50815
Pharmacist #46443

The following are posted in the lobby/waiting area: pharmacy on probation, Ask Your Pharmacist poster, translation information, and pharmacy, pharmacist, and technician licenses. Steve was working on finding a new phone translation service provider.

No food or drink was found in the refrigerator. Temperature/cleaning logs are current. Hot and cold water is available. Pharmacy compounding area is clean and organized. Pharmacy areas are restricted to authorized personnel only. Sample of water testing was completed by A.R.C.

The pharmacy hours of operation were reduced. We discussed the compounding of both chloroquine and hydroxychloroquine for Covid-19 treatment. Steve is documenting positive diagnosis on the prescription. He stated that he discussed the topic with inspector Samari and was told that this was okay so long as there is documentation on the prescription. Both medications were on the FDA drug shortage list.

Sincerely,

Oscar Tello, PharmD

PHARMACOM LLC
A Consulting Company

Pharmacy Inspection Report

Pharmacy Name	Woodland Hills Pharmacy
Date of Visit	03/20/20

License Expiration Date	02/01/21	
Does license expire within 3 months of visit?	Yes____ No___X__	Name: Date:

Pharmacy and Personnel			
	Yes	No	N/A
Pharmacy license visible	X		
Pharmacist and Technician licenses visible	X		
Pharmacy on probation sign posted and visible	X		
Ask Your Pharmacist sign posted and visible	X		
Translation services information sign posted and visible	X		
Personnel identified with badges/titles	X		
Pharmacy access is limited to authorized individuals	X		

Board Requirements			
	Yes	No	N/A
Does pharmacy keep a "State Board of Pharmacy binder"?	X		

Pharmacy and Personnel			
	Yes	No	N/A
Pharmacy Inspection Reports kept on file	X		
Pharmacy self-assessment reports (3 years maintained)	X		
Copies of employee licenses	X		
Master list of pharmacists and technician initials	X		
DEA 222 forms / Power of Attorney	X		
Executed DEA 222 forms/ CSOS receipt reports			X
DEA 106 form for theft and loss (maintained for 3 years)			X
DEA Biannual inventory	X		
DEA Quarterly reconciliation for CII medication	X		
Policies & procedures (pharmacy technicians)	X		
Policies & procedures / quality assurance program for medication errors	X		
Policies & procedures (delivery of meds when pharmacy is closed)	X		
Policies & procedures for Immunizations	X		
Policies & procedures for absence of pharmacist	X		
Protocol/licensee refuses to dispense based on ethical, moral, and/or religious grounds	X		
Purchase invoices separated (non-control, CIII-V, CII)	X		

Compounding Room Inspection Report

Board Requirements			
	Yes	No	N/A
Does pharmacy keep a "State Board of Pharmacy binder"?		X	

Pharmacy and Personnel			
	Yes	No	N/A
Compounding self-assessment reports (3 years maintained)	X		
Policies and Procedures for compounding	X		
Master Formulas	X		
Compounding worksheets	X		
End Product testing results	X		
Competency training and QA records	X		
Hood certification records	X		
Cleaning and equipment maintenance records	X		
Drug Disposal	X		
Hazardous drugs kept separate from non-hazardous drugs	X		

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA EMAIL

March 25, 2020

Dr. Steven A. Levin
CEO and Owner
Algunas Inc., dba Woodland Hills Compounding Pharmacy
20631 Ventura Blvd., Suite 305
Woodland Hills, CA 91364

Dear Dr. Levin:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our warning letter (WL# 532739) dated July 17, 2017. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter.

You are expected to take all necessary steps to ensure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

CDR Steven E Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mj

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

WARNING LETTER

Algunas Inc., dba Woodland Hills Compounding Pharmacy

MARCS-CMS 532739 – JULY 17, 2017

Recipient:

Dr. Steven A. Levin

Algunas Inc., dba Woodland Hills Compounding Pharmacy

20631 Ventura Blvd, Suite 305

Woodland Hills, CA 91364-2382

United States

Issuing Office:

Los Angeles District Office

United States

FDA U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Los Angeles, California 92612
Telephone: (949) 608-2900
Fax: (949) 608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 17, 2017

WL#: CMS 532739

Dr. Steven A. Levin, President
Algunas, Inc. DBA Woodland Hills Compounding Pharmacy
20631 Ventura Blvd, Suite 305
Woodland Hills, CA 91364-2382

Dear Dr. Levin:

From April 25, 2016, to April 29, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Algunas, Inc., dba Woodland Hills Compounding Pharmacy, located at 20631 Ventura Blvd, Suite 305 Woodland Hills, CA 91364-2382. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. Specifically, the investigator noted serious deficiencies in your practices for producing non-sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on April 29, 2016. FDA acknowledges receipt of your facility's response dated May 11, 2016. Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigator noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigator noted your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products (collectively the "ineligible drug products") that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA.

Specific violations are described below.

C. **Violations of the FDCA**

Adulterated Drug Products

The FDA investigator noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that your firm produced **(b)(4)** drug products without adequate cleaning of work surfaces, equipment, and utensils to prevent cross-contamination.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigator observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).
2. Your firm failed to have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups (21 CFR 211.42(c)).

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for the ineligible drug products that you compounded.[2] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. § 331(d)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses, and they are not exempt from the requirements of section 502(f)(1) of the FDCA (*see, e.g.*, 21 CFR 201.115). Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. It is also a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

D. Corrective Actions

We acknowledge that during our inspection of your facility, you agreed to immediately discontinue production and to no longer produce **(b)(4)** products at your firm.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

As explained above, receipt of valid prescriptions for individually-identified patients is a condition of section 503A, which your firm failed to meet for a portion of the drug products you produced. Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.

Regarding your firm's CGMP violations, your proposed corrections to improve your investigations into out-of-specification results were not adequate. For example, your investigation procedure does not provide sufficient instructions on how to conduct proper investigations into deviations from established specifications for all aspects of your operations. Moreover, your complaint handling procedure does not specify where completed investigations will be maintained and whether the information recorded will be properly reviewed for accuracy. Lastly, although you committed to ensuring that your outside laboratory used validated test methods to perform potency testing, you did not provide a date by which the use of validated test methods would begin.

E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your firm's response should be sent to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

United States Food and Drug Administration
19701 Fairchild
Irvine, California 92612

If you have any questions regarding any issues in this letter, please contact Ms. Mariza Jafary, Compliance Officer via email at Mariza.Jafary@fda.hhs.gov (mailto:Mariza.Jafary@fda.hhs.gov) by phone at (949) 608-2977 and reference unique identifier **CMS 532739**.

Sincerely,
/S/
CDR Matthew R. Dionne
Acting Director, Division of Pharmaceutical Quality Operations IV

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.
[2] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) [21 U.S.C. 321(p)] of the FDCA because they are not generally recognized as safe and effective for their labeled uses.

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA EMAIL

March 25, 2020

Dr. Steven A. Levin
CEO and Owner
Algunas Inc., dba Woodland Hills Compounding Pharmacy
20631 Ventura Blvd, Suite 305
Woodland Hills, CA 91364-2382

Dear Dr. Levin:

We are enclosing a copy of the Establishment Inspection Reports (EIRs) for the inspections conducted at your facility, Algunas Inc., dba Woodland Hills Compounding Pharmacy, located at 20631 Ventura Blvd, Suite 305, Woodland Hills, CA 91364, from April 25, 2016, to April 29, 2016, and from October 4, 2018, to October 11, 2018, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the California State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing these EIRs to you is part of this effort. The copies being provided to you comprise the narrative portions of each report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Mariza Jafary, Compliance Officer, at 949-608-2977, or by email at Mariza.Jafary@fda.hhs.gov.

Sincerely,

CDR Steven E Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP:mj

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA EMAIL

March 25, 2020

Anne Sodergren
Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento , CA 95833

Dear Ms. Sodergren:

The purpose of this letter is to refer to the California State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about practices observed during an FDA inspection at a pharmacy licensed by the California BOP, Algunas Inc., dba Woodland Hills Compounding Pharmacy, located at 20631 Ventura Blvd, Suite 305, Woodland Hills, CA 91364 (Community Pharmacy License; #PHY50815).

FDA inspected the firm from October 4, 2018, to October 11, 2018. California BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/120641/download,with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Algunas Inc., dba Woodland Hills Compounding Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

Additionally, during the inspection, the FDA investigators observed a deviation from appropriate non-sterile compounding practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, the firm's

Division of Pharmaceutical Quality Operations IV
19701 Fairchild, Irvine CA 92612-2506
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www.fda.gov

quality of water was not suitable for its intended use in the production of non-sterile drug products.

Algunas Inc. dba Woodland Hills Compounding Pharmacy committed to FDA in its response to the Form FDA 483, dated October 15, 2018, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the California State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Mariza Jafary, Compliance Officer, at 949-608-2977, or by email at Mariza.Jafary@fda.hhs.gov.

Sincerely,

CDR Steven E Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mj

Cc: Dr. Steven A. Levin, CEO/Owner
Algunas Inc., dba Woodland Hills Compounding Pharmacy
20631 Ventura Blvd Suite 305
Woodland Hills, CA 91364-2382

Phone: (818) 876-3060
Fax: (818) 876-3010
E-mail: info@woodlandhillspharmacy.com

In the meantime, we wanted to communicate that all non-sterile drug products mentioned are no longer made with water derived from the Wellsys purified drinking water system, but are instead made only with packaged Sterile Water for Irrigations.

We appreciate the inspector's time and for the guidance provided by this observation. We always strive to adhere to high quality standards in our compounding and will continue to take steps to continuously monitor our adherence to established standards.

Sincerely,

Steve Levin, RPh
Pharmacist in Charge
Woodland Hills Pharmacy

Phone: (818) 876-3060
Fax: (818) 876-3010
E-mail: info@woodlandhillspharmacy.com

Woodland Hills Pharmacy
20631 Ventura Blvd, Ste 305
Woodland Hills, CA 91364

October 15, 2018

Food and Drug Administration
19701 Fairchild
Irvine, California 92612

Re: Algunas, Inc. DBA Woodland Hills Compounding Pharmacy

To Whom It May Concern:

Receipt is acknowledged of the observation dated October 11, 2018 from the recent inspection of our pharmacy. We want to respond to the issue raised in the warning letter and provide clear information on corrective actions we will be taking and have already taken.

As described in our response below, in addition to immediately correcting the issue noted in the observation, we are taking further steps to ensure the continued integrity of our pharmacy's formulations.

FDA Observation 1: "You used a non-pharmaceutical grade component in the formulation of a drug product."

It was also noted in the observation that certain drug products had been formulated with a Wellsys brand home/office purified drinking water system rather than USP grade purified water, and that routine testing was not used to assure production quality.

After the inspection, we immediately corrected this by first switching entirely to the use of USP grade water acceptable for preparation of non-sterile drug products. The water we are now using for all formulations is packaged Sterile Water for Irrigations, with an NDC number of 00338-0004-04, which is supplied by Baxter.

In addition, we have initiated steps to install a water filtration system capable of producing USP grade purified water consistently to the pharmacy. We will be using information gathered over the coming weeks to determine the scale of the water filtration system needed to produce purified water that consistently meets USP guidelines.

B.) The firm uses non-validated test methods from a third party contract lab to perform potency testing for the release of drug products such as Amphotericin-B 0.06% Irrigation Solution, lot # 06102015@10, Amphotericin-B 0.25% Nasal Spray, lot # 06282015@2a and Baddest Topical in Town BTT 12.5 Gel, lot # 09252015@23.

Observation 2.B Response:

WHCP now understands that the testing methods used to test our products, were not a validated method. Moving forward, WHCP agrees to utilize validated test methods to perform potency testing's. We will utilize our present Analytical Laboratory or another laboratory, to become compliant with FDA regulations.

Timeline: Training date: 05/06/2016

OBSERVATION 3

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.
The Hach pH meter is calibrated at the time of use, but has not been independently calibrated. This pH meter does not have automatic temperature correction and the firm does not have other controls in place to prevent temperature variations that may affect pH measurement. The pH calibrations are not recorded in a log to monitor for trend deviations. The pH 10 standard used by the firm had expired six months prior (Hach Co. lot A4276, expiry Oct 2015.

Observation 3 Response:

WHCP reviewed information from the Hach company, which indicates that the pH meter that we presently use has an automatic temperature compensation feature. WHCP has already made arrangements to have an independent third party calibrate our pH meter. We have updated our pH Meter SOP to include daily calibration recordings in order to monitor pH calibration trends. WHCP has made a complaint with the vendor who sold us the pH meter with an expired pH solution. With that said, WHCP will be much more diligent in checking beyond use dates of solutions, especially those that come with pH meter packages.

Timeline: Training date: 05/10/16 **See Attachment 3A for Updated SOP and pH log.**

Date: 5/11/16

Steven A. Levin
President

OBSERVATION 1

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

A.) The firm's SOP titled "Handling Medication Events for Compounded Preparations" does not require the firm to review and maintain complaint files and adverse drug reports (ADE) for the drugs produced at this facility. For example, after receiving a complaint about the BTT 12.5% gel drug product, the firm did not document the complaint or maintain a log of their communication with the medical provider who reported the problem.

Observation 1.A Response:

WHCP has updated its SOP titled "Handling Medication Events for Compounded Preparations" to ensure that all employees involved with patient care are documenting complaints and adverse drug reports on forms, as well as computer patient profiles. Employees will forward these events to management for review and maintenance.

Timeline: Training date: 05/06/2016. **See Attachment 1 (a-f) for SOP updates, Pharmacy Incident and Medical event forms, Event log and Training signature log.**

B.) The firm's training SOP's do not require employees to report ADE's to the firm's management or document conversations with medical providers or patients.

Observation 1.B Response:

WHCP has updated its SOP's to ensure that all employees submit ADE's to management for review and maintenance of these records. Employees have also been trained to document conversations between both patients and physicians and enter them into patient specific profiles.

Timeline: Training date: 05/06/2016. **See Attachment 1a and 1f for SOP update and Training log.**

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

A.) The firm does not have a procedure requiring investigation into failed or rejected batches that do not meet specification. In addition, the firm does not maintain a log of failed or rejected batches and did not always conduct a root-cause analysis of the cause of the failures. Per the firm's President the firm had failed and/or rejected batches in the past two years but did not maintain records.

Observation 2.A Response:

In order to be compliant with FDA regulations, WHCP has created an SOP to address Out-of-Specification (OOS) testing results. The SOP highlights procedures to follow if a batch test fails. A root-cause analysis will be conducted to investigate batch failure. A Maintenance log for OOS results was created in order to document and track failed or rejected batches.

Timeline: Training date: 05/06/2016 **See Attachment 2 (a-d) for the OOS SOP, Form, Maintenance & Training log.**

May 11, 2016

To: Mr. Steven Porter
FDA District Director
19701 Fairchild
Irvine, CA 92612-2445
Phone: (949) 608-2900
Fax: 949-608-4417

FEI: 3011830726
Algunas Inc., DBA Woodland Hills Compounding Pharmacy
20631 Ventura Blvd, Suite 305
Woodland Hills, CA 91364-2382

EI: 4/25/2016 – 4/29/2016

Dear Mr. Porter,

The attachment to this letter is in response to observations made in the FDA 483, issued on May 2, 2016. The establishment inspection was conducted by FDA inspector Roger F. Zabinski, accompanied by FDA Inspector Kelvin X. Sanders, and California State Board Inspector Anna Yamada on April 25, 2016 through April 29, 2016. I would like to extend our appreciation for the professionalism, thoroughness, and courtesy that all the investigators afforded to us.

The following FDA 483 responses are intended to demonstrate Woodland Hills Compounding Pharmacy's (WHCP) commitment to be compliant with FDA regulations. We are committed to resolving all the issues that were observed during the inspection in a timely manner.

If you should have any questions regarding any of the responses, please do not hesitate to contact us at (855) 876-3060.

Sincerely,

Date: 5/11/16

Steven A. Levin
President

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/25/2016-4/29/2016
	FEI NUMBER 3011830726

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Steven A Levin , President	
FIRM NAME Algunas Inc., dba Woodland Hills Compounding Pharmacy	STREET ADDRESS 20631 Ventura Blvd, Suite 305
CITY, STATE, ZIP CODE, COUNTRY Woodland Hills, CA 91364-2382	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

B. The firm uses non-validated test methods from a third party contract lab to perform potency testing for the release of drug products such as Amphotericin-B 0.06% Irrigation Solution lot # 06102015@10, Amphotericin-B 0.25% Nasal Spray lot # 06282015@2a and Baddest Topical in Town BTT 12.5Gel lot #09252015@23.

OBSERVATION 3

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The Hach pH meter is calibrated at the time of use, but has not been independently calibrated. This pH meter does not have automatic temperature correction and the firm does not have other controls in place to prevent temperature variations that may affect pH measurement. The pH calibrations are not recorded in a log to monitor for trend deviations. The pH 10 standard used by the firm had expired six months prior (Hach Co. lot A4276, expiry Oct 2015).

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, Investigator X Roger F Zabinski Roger F Zabinski Investigator Signed by: Roger F. Zabinski-S	5/2/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/25/2016-4/29/2016
	FEI NUMBER 3011830726

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Steven A Levin , President	
FIRM NAME	**STREET ADDRESS**
Algunas Inc., dba Woodland Hills Compounding Pharmacy	20631 Ventura Blvd, Suite 305
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Woodland Hills, CA 91364-2382	Producer of Non-Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

A. The firm's SOP titled "Handling Medication Events for Compounded Preparations" does not require the firm to review and maintain complaint files and adverse drug reports (ADE) for the drugs produced at this facility. For example, after receiving a complaint about the BTT 12.5% gel drug product, the firm did not document the complaint or maintain a log of their communication with the medical provider who reported the problem.

B. The firm's training SOPs do not require employees to report ADEs to the firm's management or document conversations with medical providers or patients.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. The firm does not have a procedure requiring investigation into failed or rejected batches that do not meet specification. In addition, the firm does not maintain a log of failed or rejected batches and did not always conduct a root-cause analysis of the cause of the failures. Per the firm's President the firm had failed and/or rejected batches in the past two years but did not maintain records.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, Investigator X Roger F Zabinski Roger F Zabinski Investigator Signed by: Roger F. Zabinski -S	5/2/2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	10/4/2018-10/11/2018* FEI NUMBER 3011830726

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Steven A. Levin, Pharmacist-In-Charge / Owner / CEO	
FIRM NAME Algunas Inc., dba Woodland Hills Compounding Pharmacy	STREET ADDRESS 20631 Ventura Blvd Ste 305
CITY, STATE, ZIP CODE, COUNTRY Woodland Hills, CA 91364-2352	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Since 2017, rather than using USP grade purified water, your firm has been using a Wellsys brand home/office purified drinking water system which you do not routinely test to assure its production quality and contamination risks in the preparation of the following of your non-sterile drug products:

Topical Facial Pads
Clear Face Pads (Salicylic Acid 2%, Sulfacetamide 5%, Clindamycin 0.5%)
Daily Facial Peel (Pads) (Glycolic Acid 1%, Salicylic Acid 1%, Lactic Acid 3%)
Skin Lightening Pads (Hydroquinone 4%, Kojic Acid 4%, Lactic Acid 7%)
Ultra Complexion Pads (Glycolic Acid 10%, Salicylic Acid 5%)
Topical Facial Solutions
Glycolic Acid Soln
Retinoic Acid Soln
Trichloroacetic Acid Soln
Tranexamic Acid 4.8% Soln
Topical Dental Gels and Rinse
BTT 12.5 Gel ((Lidocaine 12.5%, Tetracaine 12.5%, Prilocaine 3%, Phenylephrine 3%)
Chlorhexidine 2% Gel

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator	DATE ISSUED 10/11/2018

X Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 10-11-2018 09:57:47

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	10/4/2018-10/11/2018*
	FEI NUMBER 3011830726

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven A. Levin, Pharmacist-In-Charge / Owner / CEO

FIRM NAME	STREET ADDRESS
Algunas Inc., dba Woodland Hills Compounding Pharmacy	20631 Ventura Blvd Ste 305
CITY, STATE, ZIP CODE, COUNTRY Woodland Hills, CA 91364-2352	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

Minocycline 2% Kit (in the gel)
Dyclonine 1% Rinse
Profound Gel (Lidocaine 10%, Prilocaine 10%, Tetracaine 4%)
TAC 20 ALT Gel (Lidocaine 20%, Tetracaine 4%, Phenylephrine 2%)
Enema
Short Chain Fatty Acid Enema
Sod Butyrate 100 mm/L Enema

***DATES OF INSPECTION**
10/04/2018(Thu), 10/05/2018(Fri), 10/09/2018(Tue), 10/10/2018(Wed), 10/11/2018(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator	X Rumany C Penn Investigator Signed By: 2001146009 Date Signed: 10-11-2018 09:37:47	DATE ISSUED 10/11/2018

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Attachment 1A

	Standard Operating Procedure SOP P-9.72 Handling Medication Events For Compounded Preparations	Revision: 0001 Issue Date: 5/11/16 Effective Date: 6/1/16 PIC Initials:

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure that consistent information is documented and correct steps are taken to resolve the issue when receiving communication about an event from a customer regarding a compounded preparation.

2.0 SCOPE

2.1 This procedure applies to medication related events regarding a compounded preparation. It does not apply to non-compounded preparation issues. This procedure applies to all pharmacy personnel directly involved with patient care. (Example: PSR's, RPh, Technicians and Clerks)

3.0 DEFINITIONS

3.1 PIC – Pharmacist In Charge
3.2 PSR- Patient Service Representative
3.3 Unexpected Adverse Experience – Any adverse drug experience that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity.

4.0 REFERENCES

4.1 USP-NF 795, Pharmaceutical Compounding – Non Sterile Preparations
4.2 Applicable State Regulations

5.0 RESPONSIBILITY

5.1 The Pharmacist in Charge is responsible for ensuring compliance with this procedure.

6.0 SAFETY REQUIREMENTS

6.1 N/A

7.0 REQUIRED DOCUMENTS AND FORMS

7.1 FR-P-9.72A Medication Event Form for Compounded Preparations
7.2 FR-P-9.72B Event Log for Compounded Preparations
7.3 SOP P-9.30 Recalling Compounded Preparations

8.0 PROCEDURE

8.1 Medication events must be closed by an RPh.

8.2 Form FR-P-9.72A shall be used to document any reported problem with a compounded preparation and any corrective action taken. Communication between patient or medical personnel will be documented in patient profiles.

8.3 The following are examples of when form FR-P-9.72A must be completed:

8.3.1 Patient has been advised by RPh to go to Urgent Care or Emergency Room
8.3.2 Side effects differ or are of greater severity or specificity than listed on the Patient Information Sheet
8.3.3 RPh advised patient to discontinue medication and call doctor

8.4 This procedure and form shall not be used to record non-prescription issues, (e.g., prescription turnaround time, pricing, insurance, etc.).

8.5 The person performing the investigation, following up with patient and doctor and resolution of the event is responsible for initiating a timely investigation (no later than 48 hours) for an Unexpected Adverse Experience and for ensuring that the form is completed.

8.6 This investigation will include a review of the batch record for possible anomalies. A copy of the batch record and any additional system notes will be included with the completed Medical Event Form.

8.7 If the person closing the event identifies that it may require further action, appropriate management shall be notified to participate in the determination of the appropriate steps to be taken.

8.8 The customer shall be notified as to the resolution of the event, if requested. Copies may be made of the form. It is the responsibility of the person completing the form to ensure that the latest revision of the form is used.

8.9 Immediately after completion of the form, it shall be forwarded to the attention of the Quality Department/Management for review and Maintenance.

8.10 Events will be logged onto Event Log Form FR-P- 9.72B. The event number will be taken from the log. The events will be given consecutive numbers.

9.0 RECALL OF PRODUCT

9.1 Recalls will be managed according to SOP P-9.30, Recalling Compounded Preparations.

Revision #	Reason for Change	Issue Date
0001	Updated Scope to include responsible parties.	5/11/16

APPROVAL:

PIC: DATE: 5/11/16

Attachment 1B

Medical Event Form
For Compounded Preparations
FR-P-9.72A

Issue Date: 3-2-16
Effective Date: 4-2-16
PIC: /V

Form may be copied. Ensure latest revision is used..

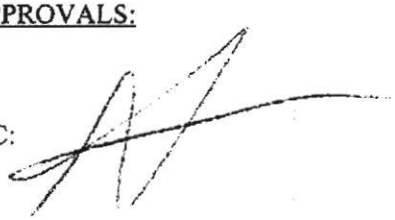
Date: Name of person recording event information:	Event # (See Event Log)
Event:	Rx Number:
Source of information (physician, customer, etc.):	Patient I.D.
Name and strength of medication:	
Known Side Effect ☐ Unexpected Adverse Experience ☐	
If known side effect, how resolved: RPh consultation ☐ Req. Change of prescription: ☐	
Consulted physician ☐ Advised pt. to consult physician ☐ Advised to stop using med(s) ☐	
Other (add comment): ☐ Comment:	
If Unexpected Adverse Experience, record explanation of occurrence including symptoms, causes, and contributing factors to the event:	
Action taken, if applicable:	
Contact information for person reporting the event:	
Patient satisfied: Yes No N/A Physician satisfied: Yes No N/A	
Name contact information for physician, if applicable:	
Date Closed: By:	

Medical Event Form
For Compounded Preparations
FR-P-9.72A

Issue Date:

Revision #	Reason for Change	Issue Date

APPROVALS:

PIC: 

Date: 3/2114

Attachment 1C

Event Log for Compounded Preparations

FR-P-9.72B

Issue Date: 3-2-16

Effective Date: 4-2-16

PIC Initials: AV

Form may be copied. Ensure latest revision is used.

Event #	Date	Product/Preparation Name	Strength	RX Number	Reason (Short description)	Recorded by/Date:

Confidential

*NR=Not Reported

Event Log for Compounded Preparations

FR-P-9.72B

Issue Date:

Revision #	Reason for Change	Issue Date

APPROVALS:

Quality:

DATE: 3/2/16

Attachment 1D

	Standard Operating Procedure SOP P-9.71 Pharmacy Incident Reporting	Revision: 0001 Issue Date: 5-5-16 Effective Date: 5-5-16 PIC Initials: AV

1.0 PURPOSE

1.1 To advance medication error prevention by carefully investigating and analyzing the cause or causes, and any contributing factors that has resulted in a medication error.

2.0 SCOPE

2.1 This procedure determines the objectives and information to be recorded in the event of a Pharmacy Incident. This procedure applies to all pharmacy personnel directly involved with patient care. (Example: PSR's, RPh, Technicians and Clerks)

3.0 DEFINITIONS

3.1 PIC – Pharmacist In Charge

3.2 PSR- Patient Service Representative

4.0 REFERENCES

4.1 USP-NF 795, Pharmaceutical Compounding – Non Sterile Preparations

4.2 Applicable State regulations

5.0 RESPONSIBILITY

5.1 It is the responsibility of the PIC to ensure that this procedure is followed.

6.0 SAFETY REQUIREMENTS

6.1 N/A

7.0 REQUIRED DOCUMENTS AND FORMS

7.1 FR-P-9.71 Pharmacy Incident Report

8.0 PROCEDURE

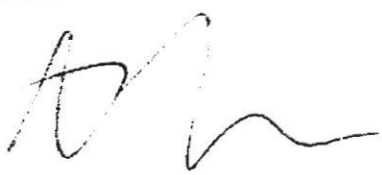
8.1 Upon receipt of information that an Incident has, or may have occurred, the pharmacy will initiate a Pharmacy Incident report using the Pharmacy Incident Report form FR-P-9.71.

8.2 The investigation will commence as soon as possible, but no later than two (2) business days from the date the incident was discovered.

8.3 Determine the causes and contributing factors to the incident.
8.4 Evaluate the most appropriate response to avoid or mitigate injury.
8.5 Identify corrective actions that will detect and prevent future similar errors from occurring.
8.6 Notify and review with all personnel involved in incident e.g. staff, patient, physician.
8.7 Initiate disciplinary action if appropriate. May include, but not limited to, oral counseling, reprimand, demotion, suspension, and/or discharge.
8.8 Data entry to be recorded:
  8.8.1 Date, location and participants in the incident review.
  8.8.2 Pertinent data and other information relating to incident.
  8.8.3 Any patient, physician and personnel notified.
  8.8.4 Findings and determinations generated by the investigation.
8.9 A record of the Pharmacy Investigation will be maintained for at least five (5) years from the recorded date.
8.10 Employees may be subject to employment discipline for failure to fully participate in the Pharmacy Incident Reporting program.
8.11 All Pharmacy Incident Reports will given to management for review.

Revision #	Reason for Change	Issue Date
0001	Updated Scope to include responsible parties.	5-5-16

APPROVALS:

PIC:  DATE: 5/5/16

Attachment 1E

Pharmacy Incident Report

FR-P-9.71

Issue Date: 3-2-16
Effective Date: 4-2-16
PIC:

Copies may be made of the form. Ensure current revision date is used.

Date Incident Occurred:	Medication Name/ Strength:	Prescription #	Report #
Patient ID Number:	Incident reported by: (✓one)Patient _____ Physician_____ Physician office staff_____ Caregiver_____ Other (specify) _____		
Date reported to pharmacy:	Location of incident (e.g., patient's home):		
Who was notified? (✓all that apply) Patient _____ Nurse _____Physician_____ Caregiver_____ Device Mfr. _____ Other (specify) _____			
Type of incident: Dispensing error (✓all that apply)incorrect drug _____ strength _____ directions_____ patient_____ other (specify) _____			
Describe incident:			
Action taken:			
Resolution:			
Report completed by/Date:	PIC signature/Date:		

Copies may be made of the form. Ensure current revision date is used.

Revision #	Reason for Change	Issue Date

APPROVAL

PIC:

DATE: 3/2/16

Attachment 1F

	Standard Operating Procedure **FR-P-2.00B** **Employee Training Record**	Issue Date: Effective Date: PIC Initials:

Form may be copied. Ensure latest revision is used.

Type of Training (✓) ones that apply	**Document ones that apply:**
SOP ✓	**SOP Number:** P-971, P-972 **Revision Number:** 0001, 0001
Form ✓	**Form Number:** _____ **Revision Number:** _____
Guidance Document ____	**Name or Reference # of Guidance Document:** P-971, P-972 @ 5-6-16
Other ____	**Name/Document # of other Training:** FR-P-971, FR-P-972A, FR-P-972B

Method of Training
(✓) ones that apply
Read ____ **Instruction and discussion** ✓ **Other (name):** _____
Comments:

Trainer (Signature): [signature] **Date of Training:** 5-6-16

Employee Name *Printed*	**Employee Signature**
Tamara Abarquez	[signature]
Anne Yambao	[signature]
Karli Klar	[signature]
Aranza Garcia	[signature]
PATRICIA LOMBAY	[signature]
Diana Blount	[signature]
Laura Moreno	[signature]
Jennie Goldstein	[signature]
Elizabeth Badal	[signature]
Leonor Suarez	[signature]
Reina Magana Meza	[signature]
Lynette Gonzalez Garcia	[signature]
Amit Sule	[signature]
Mona N Marzban	[signature]
Steve Levin	[signature]

Attachment 2A

	Standard Operating Procedure SOP P-9.41 Analytical Testing Out-of-Specification Results (OOS)	Issue Date: 5/5/16 Effective Date: 5/5/16 PIC Initials:

1.0 PURPOSE

1.1 To provide a procedure on how to investigate and document findings of a compounded preparation that does not meet specifications. To determine the cause of the Out-of-Specification (OOS) result.

2.0 SCOPE

2.1 This procedure applies to all pharmacy personnel involved in compounding products. (Example: RPh and Pharmacy technicians)

3.0 DEFINITIONS

3.1 PIC – Pharmacist-In-Charge
3.2 OOS- Out of Specification
3.3 COA- Certificate of Analysis

4.0 REFERENCES

4.1 USP-NF 795, Pharmaceutical Compounding – Non Sterile Preparations
4.2 Applicable State regulations

5.0 RESPONSIBILITY

5.1 It is the responsibility of the PIC to ensure that this procedure is followed.

6.0 SAFETY REQUIREMENTS

6.1 N/A

7.0 REQUIRED DOCUMENTS AND FORMS

7.1 FR-P-9.41A
7.2 FR-P-9.41B
7.3 Testing Results from Analytical Laboratory

8.0 PROCEDURE

8.1 Review Test results of compounded preparation obtained from the Analytical Laboratory.
8.2 Quarantine any remaining product.
8.3 Recall products (if distributed).
8.4 Fill out form FR-P-9.41A to document investigation.
8.5 Fill out from FR-P-9.41B to log failed or rejected preparations.
8.6 Investigate possible reasons for the OOS results.
8.7 List any reasons to determine where any errors could have contributed to the OOS results. (Example: Measuring, weighing, mixing, ingredient COA)
8.8 Once errors have been identified, make appropriate changes to Master Formula.
8.9 Close out OOS investigation by having quality/management person review investigation.
8.10 Test new formula before products are to be released.

Revision #	Reason for Change	Issue Date
	New Procedure	5-5-16

APPROVALS:

PIC: _____ DATE: 5/5/16

Attachment 2B

Out of Specification Report Form
FR-P-9.41A

Issue Date: 5/5/16
Effective Date: 6/5/16
PIC: N

Form may be copied. Ensure latest revision is used..

Date: Name of person recording event information:	OOS # (See OOS Log)
Compounded Product:	Batch Number:
Description of OOS:	
Compound record Review: (Circle) Yes No Comments:	
Calculation Review: (Circle) Yes No Comments:	
Review of Compounding Process: (Circle) Yes No Comments:	
Review of Ingredients used in Compounded preparation: (Circle) Yes No Comments:	
Review of Storage and Shipping Conditions: (Circle) Yes No Comments:	
Quarantine Compounded preparation: (Circle) Yes No Comments:	
Recall affected Compounded preparations (if distributed): (Circle) Yes No Comments:	
Destruction of Compounded preparation: (Circle) Yes No Comments:	
List of Reasons that may have led to OOS:	
Action taken, if applicable:	
Date Closed: By:	

Out of Specification Report Form
FR-P-9.41A

Issue Date:

Revision #	Reason for Change	Issue Date

APPROVALS:

PIC: [signature]

Date: 5/5/16

Attachment 2C

OOS Log for Compounded Preparations

FR-P-9.41B

Issue Date: 5/5/16
Effective Date: 6/5/16

PIC Initials: N

Form may be copied. Ensure latest revision is used.

OOS #	Date	Product/Preparation Name	Strength	RX Number	Reason (Short description)	Recorded by/Date:

Confidential

*NR=Not Reported

OOS Log for Compounded Preparations

FR-P-9.41B

Issue Date:

Revision #	Reason for Change	Issue Date

APPROVALS:

Quality:

DATE: 5/5/16

Attachment 2D

	Standard Operating Procedure FR-P-2.00B **Employee Training Record**	Issue Date: Effective Date: PIC Initials:

Form may be copied. Ensure latest revision is used.

Type of Training (✓) ones that apply	**Document ones that apply:**
SOP ✓	**SOP Number:** 9.41 **Revision Number:** ____
Form ✓	**Form Number:** FR-P-9.41A **Revision Number:** ____
Guidance Document ____	**Name or Reference # of Guidance Document:** ____
Other ____	**Name/Document # of other Training:** FR-P-9.41B

Method of Training
(✓) ones that apply
Read ✓ **Instruction and discussion** ✓ **Other (name):** ____
Comments:

Trainer (Signature): George Suarez [signature]	**Date of Training:** 5-6-16
Employee Name *Printed*	**Employee Signature**
Rosa Magana Meza	[signature]
Janette Gonzalez Ercine	[signature]
Amit Sule	[signature]
George Suarez	[signature]
Mona N. Marzban	[signature]
Steve L-Pvin	[signature]

Attachment 3A

	Standard Operating Procedure SOP P-6.20 pH Meter, Use, Care, Cleaning and Calibration	Revision: 0001 Issue Date: 5/10/16 Effective Date: 6/10/16 PIC Initials: N

1.0 PURPOSE

1.1 To provide for the use, standardization, and care of a pH meter and also to ensure that the pH meter is calibrated prior to use.

2.0 SCOPE

2.1 This procedure provides the information and steps needed to use, calibrate, maintain, and clean the pH Meter used in compounding processes.

3.0 DEFINITIONS

3.1 PIC – Pharmacist In Charge

4.0 REFERENCES

4.1 USP-NF 795, Pharmaceutical Compounding – Non Sterile Preparations
4.2 Applicable State regulations

5.0 RESPONSIBILITY

5.1 It is the responsibility of the PIC to ensure employees are trained and this procedure is followed.

6.0 SAFETY REQUIREMENTS

6.1 N/A

7.0 REQUIRED DOCUMENTS AND FORMS

7.1 FR-P-6.20 pH Meter Log

8.0 PROCEDURE

8.1 **Equipment/Supplies Required:**
- 8.1.1 pH Meter
- 8.1.2 Buffer Solutions: pH 4, pH 7 and pH 10.

8.2 **Use**

8.2.1 Use a pH meter with a readability of at least ± 0.01 pH units.

8.2.2 Standardize the pH meter at each use prior to compounding products.

8.2.3 Allow sufficient stabilization time for each measurement.

8.3 **Care of the Electrode**

8.3.1 Keep the pH meter in the storage case.

8.4 **Cleaning and Storage of the pH Meter Electrode**

8.4.1 Rinse electrodes with distilled water or deionized water and blot dry.

8.4.2 Store glass pH electrodes in Electrode Storage Solution. (if applicable)

8.5 **Calibration**

8.5.1 Perform a daily calibration of pH meter(s) each morning prior to taking pH readings of any compounds.

8.5.2 Calibration readings each buffer solution, shall be documented on the appropriate log for verification.

8.5.3 Depending on which pH meter is being used, the calibration steps will vary. Refer to the manual for individual pH meter instructions.

8.5.4 Calibration should be documented for pH 4, pH 7, and pH 10 buffer solutions.

8.5.5 Date, Model, and Model# of pH meter should be recorded on log sheet.

8.5.6 **Calibration procedure**

8.5.6.1 Press power button to turn on pH meter.

8.5.6.2 Place a few drops of desired buffer solution for calibration.

8.5.6.3 Press the calibrate button to start calibration.

8.5.6.4 Record calibration reading on Daily Calibration Log.

8.5.6.5 Repeat steps above for other buffer solutions.

8.5.6.6 Clean electrodes according to cleaning procedures.

8.6 **Standardization:**

8.6.1 Standardizing for pH measurement: Because electrodes vary in their response, you must standardize your pH meter and electrode to compensate for electrode variation. The more frequently you standardize, the more accurate your measurements. Standardize daily, or more often for accurate results.

8.6.2 Start the standardization using pH 7 buffer solution.

8.6.3 Rinse the electrodes with a portion of distilled water or a portion of the standard buffer solution to be used.

8.6.4 Follow calibrating procedures in 8.5.6 above using pH 7 buffer solution.
8.6.5 Record calibration reading on compounding work sheet.
8.6.6 Clean electrodes according to cleaning procedures.

8.7 **General Information**

8.7.1 Carefully stirring the sample may provide a more representative pH reading, fast response, and the minimization of a very slight alkaline effect from the glass bulb. Temperature should be consistent throughout the measurement as temperature may change the pH reading. The pH meter chosen should have automatic temperature compensation as a feature.

Revision #	Reason for Change	Issue Date
0001	Daily calibration log procedure and reference to temperature	
	compensation was added.	

APPROVALS:

PIC: DATE: 5/10/16

PH Meter Daily Calibration Log

Issue Date: 5/10/16
Effective Date: 6/10/16

FR-P-6.20

PIC Initials: N

Month/Year:
____/____

pH Meter #1 Model:_____ Model#:_____					pH Meter #2 Model:_____ Model#:_____				
Date	**Control Solution pH 4**	**Control Solution pH 7**	**Control Solution pH 10**	**Initials**	**Date**	**Control Solution pH 4**	**Control Solution pH 7**	**Control Solution pH 10**	**Initials**
01					01				
02					02				
03					03				
04					04				
05					05				
06					06				
07					07				
08					08				
09					09				
10					10				
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31					31				

Verified by: _____ Date: _____

Approvals:

PIC:  Date: 5/10/16

IF 36620

IN THE MUNICIPAL COURT OF LONG BEACH JUDICIAL DISTRICT
COUNTY OF LOS ANGELES, STATE OF CALIFORNIA

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff,
v.
STEVEN ARTHUR LEVIN
Defendant.

No. A-026 766

COMPLAINT
FELONY
11360 H&S

PRL W/D 5-16

Personally appeared before me this 22nd day of March, 1983
L. Wallace
of the County of Los Angeles, who being first duly sworn on oath, upon information and belief complains and says:

That on or about the 20th day of March, 1983, at and in the County of Los Angeles, State of California, the crime of **VIOLATION OF SECTION** 11360, Health and Safety Code, a felony, was committed by

STEVEN ARTHUR LEVIN

who did willfully and unlawfully transport, import into the State of California, sell, furnish, administer, and give away, and offer to transport, import into the State of California, sell, furnish, administer, and give away, and attempt to import into the State of California and transport marijuana.

$ 1,000.00
Surety Bond/~~Cash Bail~~
Posted on Date 3.20.83
Bond # B07.276909
Receipt #
Surety Co. Amwest
Depositor:

AA 2
3.28

Subscribed and sworn to before me on

3-22-83

Issued by ROBERT H. PHILIBOSIAN District Attorney
By Deputy

Bail Recommended $1,000.

WITNESSES JAMES COSPER
LBPD
LONG BEACH BRANCH/bas
DEFT. IN CUSTODY

cii unk
OFFS. - 30 min.

FILED
MAY 12 1983

4-21
3-28-83
4-21-83
W/T

IN THE MUNICIPAL COURT OF LONG BEACH JUDICIAL DISTRICT
COUNTY OF LOS ANGELES, STATE OF CALIFORNIA

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff,

v.

STEVEN ARTHUR LEVIN

Defendant.

Case No. A026766

CERTIFICATE AND ORDER OF MAGISTRATE

GUILTY PLEA TO FELONY

I, the undersigned, judge of the above-named court, do hereby certify: that the complaint attached hereto was filed in the above-named court on 3-22-83; that on 5-10-83 while the charge(s) in said complaint remained pending in the above-named court, the defendant STEVEN ARTHUR LEVIN with counsel J. BROTT, appeared before me in open court; that I read the said complaint to said defendant; and that I then asked the said defendant whether he pleaded guilty to the offense(s) charged in said complaint.

Whereupon, with my consent and the consent of Deputy District Attorney DONOGHUE, and while said defendant's counsel was still present in court, the said defendant pleaded guilty to the following offense(s) charged in said complaint, to wit:

11360 H&S TRANSPORT/IMPORT/SELL MARIJUANA.

FILED
MAY 12 1983
[illegible] Clerk
[illegible]

committed on or about 3-20-83, in the County of Los Angeles, State of California.

Count(s) XXX dismissed on motion of the people.

By reason of the foregoing, I hereby certify this case to the Superior Court of the State of California, in and for the County of Los Angeles [redacted]. Bail is set in the sum of $ 1,000.00

P.A. $

BOND TO STAND

Total for Release $ 1,000.00

Further proceedings set for 6-14-83, at 9:00 A.M., in Dept. No. F of the SOUTH Branch, Superior Court in and for said County of Los Angeles.

I further certify that the foregoing is a true and correct record of all proceedings had before me this date in said case, and that attached hereto are copies of all proceedings held in the above-named court in said case.

5-10-83

Judge
MARCUS O. TUCKER

DISTRIBUTION: Original to Superior Court, one copy to Sheriff, one copy to District Attorney, one copy to file.

CERTIFICATE AND ORDER OF MAGISTRATE - GUILTY PLEA TO FELONY

[illegible] P.C. 859a, 877a

3 PAS

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

Date JUN 14 1983 DEPT. SOF

HONORABLE ERNEST L KELLY JUDGE | F CURRY Deputy Clerk

305 J GIBSON Deputy Sheriff | C MARTINO Reporter

CASE NO. [illegible] (Parties and counsel checked if present)

PEOPLE OF THE STATE OF CALIFORNIA — Counsel for People: DEPUTY DISTRICT ATTY B DELONG ✓

vs

CHARGE 11 LEVIA STEVEN ARTHUR ✓ — Counsel for Defendant: J BROTT APT ✓

H11360 DICTS

BOX CHECKED IF ORDER APPLICABLE # 955066

NATURE OF PROCEEDINGS: BAIL

71 ☐ P&S

72 ☐ ..... IS SWORN AS THE ENGLISH ..... INTERPRETER

73 ☐ — CRIMINAL PROCEEDINGS ADJOURNED/RESUMED

74 ☐ DEFENDANT ORDERED DELIVERED TO DEPARTMENT OF CORRECTIONS PER SECTION 1203.03 PENAL CODE

75 ☒ ON 6-14-83 MOTION PROBATION AND SENTENCE HEARING CONTINUED TO 12-14-83

AT 9 A.M. IN DEPT. SO-F ☒ SUPPLEMENTAL PROBATION REPORT/PROGRESS REPORT ORDERED

76 ☐ DEFENDANT PERSONALLY AND ALL COUNSEL WAIVE TIME FOR SENTENCING

77 ☐ — PROBATION DENIED. SENTENCE IS IMPOSED AS FOLLOWS

☐ IMPRISONED IN STATE PRISON FOR ☐ TERM PRESCRIBED BY LAW ☐ TOTAL OF ..... YEARS

☐ COURT SELECTS (NC) ..... TERM OF ..... YEARS FOR THE BASE TERM AS TO COUNT .....

☐ PLUS ..... YEARS PURSUANT TO PENAL CODE SECTION .....

☐ PLUS ..... AS INDICATED IN BOX 87 BELOW

☐ COMMITTED TO CALIFORNIA YOUTH AUTHORITY. THE TERM OF IMPRISONMENT TO WHICH THE DEFENDANT WOULD HAVE BEEN SENTENCED PURSUANT TO SECTION 1170 PENAL CODE IS ..... YEARS

☐ IMPRISONED IN LOS ANGELES COUNTY JAIL FOR TERM OF .....

☐ FINED IN SUM OF $ ..... PLUS ASSESSMENT TO BE PAID TO COUNTY CLERK

78 ☐ SENTENCE IS SUSPENDED.

79 ☒ — PROCEEDINGS SUSPENDED.

80 ☒ PROBATION GRANTED FOR A PERIOD OF 3 YEARS. (SEE CONDITIONS LISTED BELOW).

81 ☐ — PROBATION TO BE WITHOUT FORMAL SUPERVISION.

☒ — SPEND FIRST 45 days IN COUNTY JAIL ☐ ROAD CAMP OR HONOR FARM RECOMMENDED

☐ WORK FURLOUGH PROGRAM RECOMMENDED ☐ NOT TO BE ELIGIBLE FOR COUNTY PAROLE

☒ PAY FINE OF $ 45 [illegible] ☐ [illegible] ASSESSMENT

[illegible] PURSUANT TO SECTION [illegible] PENAL CODE ☐ [illegible]

ASSESSMENT TO BE PAID TO [illegible] PROBATION OFFICER IN SUCH AMOUNT AND MANNER AS HE SHALL PRESCRIBE

☐ — MINIMUM PAYMENT OF FINE/RESTITUTION TO BE $ .....

☐ MAKE RESTITUTION THROUGH PROBATION OFFICER IN SUCH AMOUNT AND MANNER AS HE SHALL PRESCRIBE

☐ TOTAL AMOUNT OF RESTITUTION TO INCLUDE A 2% SERVICE CHARGE AS AUTHORIZED BY SECTION 903 WELFARE & INST. CODE

☐ — NOT DRINK ANY ALCOHOLIC BEVERAGE AND STAY OUT OF PLACES WHERE THEY ARE THE CHIEF ITEM OF SALE.

☒ NOT USE OR POSSESS ANY NARCOTICS, DANGEROUS OR RESTRICTED DRUGS OR ASSOCIATED PARAPHERNALIA, EXCEPT WITH VALID PRESCRIPTION, AND STAY AWAY FROM PLACES WHERE USERS CONGREGATE.

☒ — NOT ASSOCIATE WITH PERSONS KNOWN BY YOU TO BE NARCOTIC OR DRUG USERS OR SELLERS.

☐ SUBMIT TO PERIODIC ANTI-NARCOTIC TESTS AS DIRECTED BY THE PROBATION OFFICER

☐ — HAVE NO BLANK CHECKS IN POSSESSION, NOT WRITE ANY PORTION OF ANY CHECKS, NOT HAVE BANK ACCOUNT UPON WHICH YOU MAY DRAW CHECKS.

☐ NOT GAMBLE OR ENGAGE IN BOOKMAKING ACTIVITIES OR HAVE PARAPHERNALIA THEREOF IN POSSESSION, AND NOT BE PRESENT IN PLACES WHERE GAMBLING OR BOOKMAKING IS CONDUCTED

☐ — NOT ASSOCIATE WITH .....

☐ COOPERATE WITH PROBATION OFFICER IN A "LINE UP" FOR .....

☐ — SUPPORT DEPENDENTS AS DIRECTED BY PROBATION OFFICER

☒ SEEK AND MAINTAIN TRAINING, SCHOOLING OR EMPLOYMENT AS APPROVED BY PROBATION OFFICER

☒ — MAINTAIN RESIDENCE AS APPROVED BY PROBATION OFFICER .....

☐ SURRENDER DRIVER'S LICENSE TO CLERK OF COURT TO BE RETURNED TO DEPARTMENT OF MOTOR VEHICLES

☐ — NOT DRIVE A MOTOR VEHICLE UNLESS LAWFULLY LICENSED AND INSURED

☐ NOT OWN, USE OR POSSESS ANY DANGEROUS OR DEADLY WEAPONS

☒ — SUBMIT PERSON AND PROPERTY TO SEARCH OR SEIZURE AT ANY TIME OF THE DAY OR NIGHT BY ANY LAW ENFORCEMENT OFFICER WITH OR WITHOUT A WARRANT

☒ OBEY ALL LAWS, ORDERS, RULES AND REGULATIONS OF THE PROBATION DEPARTMENT AND OF THE COURT

☒ — PAY COSTS OF PROBATION SERVICES IN AN AMOUNT AND MANNER AS DETERMINED BY PROBATION OFFICER.

82 ☐ DEFENDANT TO BE GIVEN CREDIT FOR ..... DAYS IN CUSTODY (INCLUDES ..... DAYS GOOD TIME/WORK TIME)

83 ☐ — SENTENCE/COUNTS TO RUN CONSECUTIVELY TO/CONCURRENTLY WITH .....

84 ☒ STAY OF EXECUTION GRANTED TO 12-14-83 SO-F 9:00 AM

85 ☐ — ON MOTION OF PEOPLE COUNTS ..... DISMISSED IN FURTHERANCE OF JUSTICE

86 ☐ COURT ADVISES DEFENDANT OF HIS APPEAL/PAROLE RIGHTS.

87 ☒ — FURTHER ORDER AS FOLLOWS/ADDITIONAL CONDITIONS OF PROBATION:

Defendant is ordered to register with his local law enforcement agency.

Defendant is ordered to perform 100 hours of community service through the discretion of the probation officer.

The court accepts the certified plea from municipal court.

88 ☐ — SHERIFF IS ORDERED TO ALLOW DEFENDANT ..... PHONE CALLS AT DEFENDANT'S OWN EXPENSE.

89 ☐ DEFENDANT FAILS TO APPEAR WITH/WITHOUT SUFFICIENT EXCUSE ☐ BAIL FORFEITED ☐ O.R. REVOKED

90 ☐ — [illegible] WARRANT ORDERED [illegible] ☐ NO BAIL ☐ BAIL FIXED AT $

91 ☐ DEFENDANT APPEARING BENCH WARRANT ORDERED RECALLED/QUASHED ☐ RECALL NO ..... WRITTEN ☐ ABSTRACT FILED

☐ REMANDED ☐ BAIL ☒ BAIL EXON ☒ BOND NO AO? 276 904

☐ RELEASED ☐ O.R. ☐ O.R. DISCHARGED ☒ ON PROBATION (STAY 12-14-83)

☐ IN CUSTODY OTHER MATTER

MINUTES ENTERED 6-14-83 COUNTY CLERK

3 PAS

DATE NOTICE MAILED 14, 34, 19, 57 MINUTE ORDER

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

MISC.

Date DEC 14, 1983 | DEPT. 30

HONORABLE ERNEST L. KELLY, JUDGE | F. TAYA J, Deputy Clerk

402 | L. GIBSON, Deputy Sheriff | C. WOLF, Reporter

CASE NO. A026766

PEOPLE OF THE STATE OF CALIFORNIA
vs
01 DEVIN STEVEN ARTHUR

CHARGE: HI1360 01CT

X 955066

(Parties and counsel checked if present)

Counsel for People: DEPUTY DISTRICT ATTY E. J McDonald

Counsel for Defendant: J Brott, Pvt

(BOX CHECKED IF ORDER APPLICABLE)

NATURE OF PROCEEDINGS: DISPOSITION OR STAY of 6-14-83

101 ☐ IS SWORN AS THE ENGLISH INTERPRETER 6-14-83
102 ☐ PUBLIC DEFENDER APPOINTED, D.P.D./
103 ☐ DUE TO CONFLICT OF INTERESTS, PUBLIC DEFENDER RELIEVED, PURSUANT TO SECTION 987.2 PENAL CODE. IS APPOINTED
104 ☐ DEFENDANT IS ADVISED OF RIGHTS RE HEARING ON VIOLATION. DEFENDANT ADMITS VIOLATION OF PROBATION AND WAIVES RIGHTS TO REVOCATION HEARING.
105 ☐ DEFENDANT IS FOUND TO BE/NOT TO BE IN VIOLATION OF PROBATION.
106 ☐ PROBATION IS REVOKED/REMAINS REVOKED; SENTENCE IMPOSED AS FOLLOWS: (SEE BOX)
107 ☒ PROBATION REINSTATED/CONTINUED ON SAME TERMS AND CONDITIONS, EXCEPT FOR MODIFICATION. (SEE BOX 114)
108 ☐ PROBATION GRANTED FOR A PERIOD OF ____ YEARS. (SEE CONDITIONS BELOW/ATTACHED)
109 ☐ PROBATION IS EXTENDED TO
110 ☐ ON ____ MOTION, FURTHER PROCEEDINGS CONTINUED TO ____ AT ____ A.M. IN DEPT ____ ( ) NON-APPEARANCE CALENDAR
111 ☐ DEFENDANT INSTRUCTED TO RETURN ON ABOVE DATE
112 ☐ SUPPLEMENTAL PROBATION REPORT IS ORDERED
113 ☐ DEFENDANT PERSONALLY AND ALL COUNSEL WAIVE TIME FOR
114 ☒ FURTHER ORDERS AS FOLLOWS: Defendant placed on summary probation, and is to be registered with CII. County Jail time of 45 days previously stayed to this date, is now ordered set aside.

115 ☐ SENTENCE/COUNTS TO RUN CONSECUTIVELY/CONCURRENTLY WITH
116 ☐ DEFENDANT TO BE GIVEN CREDIT FOR ____ DAYS IN CUSTODY (INCLUDES ____ DAYS GOOD TIME/WORK TIME)
117 ☐ COURT ADVISES DEFENDANT OF HIS APPEAL/PAROLE RIGHTS
118 ☐ SHERIFF IS ORDERED TO ALLOW DEFENDANT ____ PHONE CALLS AT DEFENDANT'S OWN EXPENSE.
119 ☐ CRIMINAL PROCEEDINGS ADJOURNED.
120 ☐ DEFENDANT ORDERED DELIVERED TO DEPARTMENT OF CORRECTIONS PURSUANT TO SECTION 1203.03 PENAL CODE.
121 ☐ FURTHER PROCEEDINGS CONTINUED TO ____ AT ____ A.M. IN DEPT.
122 ☐ EXECUTION OF SENTENCE IS SUSPENDED. PETITION ORDERED FILED IN DEPARTMENT 95 PURSUANT TO SECTION 3051 WELFARE AND INSTITUTIONS CODE. FURTHER PROCEEDINGS CONTINUED TO ____ AT 10:00 A.M. IN DEPARTMENT 95.
123 ☐ COUNSEL AND DEFENDANT ARE ORDERED TO APPEAR IN DEPARTMENT 95 ON THE ABOVE DATE
124 ☐ FURTHER PROCEEDINGS CONTINUED TO ____ AT 9:00 A.M. IN THIS DEPARTMENT.
125 ☐ DEFENDANT HAVING BEEN COMMITTED BY DEPARTMENT ____ PURSUANT TO SECTION 3051 WELFARE AND INSTITUTIONS CODE, C.R.C. NUMBER ____ MATTER IS ORDERED OFF CALENDAR.

PAYMENT OF DOCTOR/ATTORNEY/INVESTIGATOR/EXPERT WITNESS:
126 ☐ THE COURT HAVING APPOINTED ____ ON ____

PAY CODE: PURSUANT TO SECTION(S) ____ AND SERVICE HAVING BEEN RENDERED / COMPLETED ON ____ THE COURT FINDS THAT $ ____ IS A REASONABLE SUM FOR COMPENSATION AND NECESSARY EXPENSES AND ORDERS A WARRANT BE DRAWN BY THE AUDITOR ON THE TREASURER FOR SAID SUM IN FAVOR OF
NAME
ADDRESS
SERIAL NUMBER ____ CITY, STATE, ZIP ____ SOCIAL SECURITY/TAX I.D. NUMBER

127 ☐ PURSUANT TO SECTION 17 PENAL CODE, OFFENSE IS DEEMED TO BE A MISDEMEANOR
128 ☐ PROBATION IS ORDERED TERMINATED PURSUANT TO SECTION 1203.3 PENAL CODE.
129 ☐ PLEA OF GUILTY OR CONVICTION IS SET ASIDE, A PLEA OF NOT GUILTY IS ENTERED; CASE IS DISMISSED PURSUANT TO SECTION 1203.4 PENAL CODE.
130 ☐ DEFENDANT'S EX PARTE REQUEST/MOTION FOR ____ IS DENIED/GRANTED. DEFENDANT NOTIFIED BY U.S. MAIL.
131 ☐ DEFENDANT FAILS TO APPEAR WITH/WITHOUT SUFFICIENT EXCUSE. ( ) BAIL FORFEITED / ( ) O.R. REVOKED
132 ☐ BENCH WARRANT ORDERED ISSUED/AND HELD UNTIL ____ NO BAIL/BAIL FIXED AT $
133 ☐ BENCH WARRANT RECALLED/QUASHED ( ) RECALL $ ____ ISSUED ( ) WARRANT/ABSTRACT FILED
134 ☐ UPON PAYMENT of $ ____ COSTS BEFORE ____ $ ____ COSTS HAVING BEEN PAID TIMELY RECEIPT # ____ ORDER OF ____ FORFEITING BAIL IS/IS TO BE VACATED AND BAIL EXONERATED
135 ☐ BAIL SET AT

☐ REMANDED ☐ BAIL ☐ BAIL EXON. ☐ BOND NO.
☐ RELEASED ☐ O.R. ☐ O.R. DISCHARGED ☐ IN CUSTODY OTHER MATTER
MINUTE ORDER ☒ ON PROBATION Summary

MINUTES ENTERED

MSC 770
CHG (REV. 7/82) TR2

Woodland Hills Compounding Pharmacy
Algunas, Inc.
Call Toll Free: 855-876-3060
20631 Ventura Blvd., Suite 305 • Woodland Hills, CA 91364

Rx# 501700 -N

TEST, JOHN TESTDOC, TESTDOC
123 CANOGA, WOODLAND HILLS CA 91364
CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER

NDC:
30 GM Lot# LG16123 Discard after 12/02/20
USE AS DIRECTED.

A. Sule **06/11/20** **0 refills before 06/11/21**

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.

SHEETED DUO-WEB STYLE Y
Labels Manufactured By
Rx Systems, Inc. • 1-800-922-9142

STORE AT ROOM TEMPERATURE
COMPOUNDED BY WOODLAND HILLS PHARMACY
CONTAINS ALTERNATIVE TO MUCOLOX
REFRIGERATE UPON ARRIVAL

Rx# 501700 -N **TESTDOC, TESTDOC**
20631 Ventura Blvd Ste 305, Woodland Hills CA 91364

06/11/20 AS/RM
TEST, JOHN **TESTDOC, TESTDOC**
123 CANOGA, WOODLAND HILLS CA 91364 **02/07/1992**
CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER

NDC:
30 GM Lot# LG16123 Discard after 12/02/20
USE AS DIRECTED.

A. Sule **06/11/20** **0 refills before 06/11/21**

Rx# 501700 -N **TESTDOC, TESTDOC**
TEST, JOHN
CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER
30 GM **06/11/20**

TEST, JOHN
123 CANOGA
Woodland hills CA
91364
Pt Phone: [818] 568-0033

Rx# 501700 -N **06/11/20** (__)Counseled (__)Refused
TEST, JOHN
CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER
X

Woodland Hills Compounding Pharmacy
Algunas, Inc.
Call Toll Free: 855-876-3060
20631 Ventura Blvd., Suite 305 • Woodland Hills, CA 91364

Woodland Hills Compounding Pharmac
Algunas, Inc.
Call Toll Free: 855-876-3060
20631 Ventura Blvd., Suite 305 • Woodland Hills, CA 91364

New

TEST, JOHN
123 CANOGA
Woodland hills CA
91364

Rx# 501700 -N 30 GM

CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER

TESTDOC, TESTDOC
20631 Ventura Blvd Ste 305, Woodland Hills CA 91364
[855] 876-3060
06/11/20
Self Pay HIPAA check
0.00
Sales tax

Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.

Woodland Hills Compounding Pharmac
Algunas, Inc.
Call Toll Free: 855-876-3060
20631 Ventura Blvd., Suite 305 • Woodland Hills, CA 91364

New

TEST, JOHN
123 CANOGA
Woodland hills CA
91364

Rx# 501700 -N 30 GM

CHOLESTYRAMINE [MIX] 8 GRAMS 4GM/8GM POWDER

Please Call To Receive An Oral Consultation Provided By Our Pharmacist.

YOUR PRESCRIPTION HAS BEEN COMPOUNDED BY WOODLAND HILLS PHARMACY

Thank You,
We Appreciate Your Business

THIS IS YOUR RECEIPT. PLEASE RETAIN FOR YOUR TAX OR INSURANCE.