### **New Nonresident Pharmacy Application Review**

Name:	Professional Partners, Inc.
DBA:	Westcliff Compounding Pharmacy
Street Address:	1901 Westcliff Drive
City, State, Zip:	Newport Beach, California 92660
Date application received:	July 7, 2015
Application reviewed by:	Sue Mears
Date application reviewed:	July 8, 2015
Omission(s):	None
Area(s) of Concern:	Disclosed discipline, summarized below

Pharmacy was disciplined by the Colorado Board of Pharmacy in November 2013 for shipping 909 prescription drugs into Colorado without prescription orders over a two year period. The pharmacy had been shipping compounded medications to a prescriber for office use, which it thought to be allowable. The pharmacy agreed to a \$6,600 fine and to only dispense compounded medications into Colorado pursuant to a patient-specific prescription.

#### **UPDATE:**

During this board's review of the pharmacy's application at its August / September meeting, the board was concerned about the pharmacy's response to the question of registering and reporting to the PMP for compounded controlled substances. The board asked for further follow up with the pharmacy. The pharmacist explained that if a controlled substance is compounded with a non-controlled substance, he believed the resulting compound to be non-controlled. It was explained to him that the Iowa PMP requires submission of all controlled substances dispensed to Iowa, regardless of final form. He understood and agreed that his pharmacy will register and report to the PMP all compounded medications that contain controlled substances.

Ple	ase	e type or print clearly in ink. Make changes as necessary.
1		PPLICATION FOR:  Renewal New □ Address Chg. □ Name Chg. □ Ownership Chg. □ Pharmacist in Charge Chg.
		OR LICENSE PERIOD: DWA PHARMACY LICENSE NO.: LICENSE FEE: \$135.00
2	Ad	BA, LEGAL NAME, & LOCATION OF PHARMACY:    PLOFESSIONAL PHARMACY, INC.    IMA WESTCLIFF COMOUNDING PHARMACY    IGNI WESTCLIFF IN #3A   Remit check or money order payable to:   IOWA BOARD OF PHARMACY   (DO NOT SEND CASH)    PLOFESSIONAL PHARMACY   IOWA BOARD OF PHARMACY   (DO NOT SEND CASH)
3		HARMACY PHONE (949) 272 0) XFAX (949) 272 8 FED. TAX ID: 9005996
J		-MAIL ADDRESS DEA NO.:
4		YPE OF OWNERSHIP: ☐ Individual ☐ Partnership (A)Corporation ☐ Other
5	P	HARMACIST IN CHARGE:
		AME LICENSE NO. HRS WORKEDWEEK SIGNATURE
6		TTACH THE FOLLOWING INFORMATION:
	a) b) c) d) e) f)	List of the names, titles, and addresses of all principal owners, partners, and officers of the pharmacy. List of all staff pharmacists currently employed (include home state license number and average hours worked per week for each).  List of all technicians, pharmacist-interns, and pharmacy support persons currently employed (include home state license or registration number and average hours worked per week for each).  Copy of current license, permit, or registration certificate issued by the home state regulatory authority. Most recent inspection report resulting from an inspection conducted by the home state regulatory authority. Evidence of correction of any noncompliance noted on the inspection report by the home state. A copy of a prescription label that includes the toll-free number for use by lowa patients. A typed description of the prescription drugs and services provided to patients in lowa.
7		RIMINAL HISTORY:
		Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) been convicted of any crimes (felonies or misdemeanors)? Exclude traffic violations and alcohol-related offenses classified as misdemeanors.  Yes No If yes, attach explanation.
	b)	Has the pharmacist in charge been convicted of any crimes (felonies or misdemeanors)? Exclude traffic violations and alcohol-related offenses classified as misdemeanors.  Yes No If yes, attach explanation.
8	D	<b>ISCIPLINARY HISTORY: (NOTE:</b> Discipline includes, but is not limited to: citations, reprimands, fines, license restrictions, probation, and license or registration surrender, suspension, and revocation.)
re	a)	Has the pharmacy, the pharmacy's owner, or any officer or partner (if the pharmacy is owned by a corporation or partnership) ever been disciplined by any licensing authority?
	b)	Has the pharmacist in charge ever been disciplined by any licensing authority?  Yes No If yes, describe the discipline and attach all relevant disciplinary documents.

 $\eta_{i}$ 

Has the pharmacy or the pharmacist in charge ever been denied a license by any licensing authority? Yes		c)	Does the pharmacy, the pharmacy, the pharmacy, or knowledge of a Yes Yes No	any complaints or invest	igations, pendin		
a) What are the regular hours of operation of the pharmacy for each period/day identified?  Monday-Friday: Saturday: Saturday: Sunday: Sunday: What are the hours of operation of the holl-free phone number?  Monday-Friday: Saturday: Sunday: Sunday: Sunday: Sunday: Sunday: Monday-Friday: Saturday: Sunday: Sunda		d)				a license by an	y licensing authority?
c) What are the hours of operation of the toll-free phone number?  Monday-Friday:	9	a)	What are the regular hours	of operation of the pha	rmacy for each	period/day ider Sunda	ntified? ay:
Monday-Friday:						ust be printed	on prescription label)
have access to patient records at the time of the call?  Yes No			Monday-Friday:	30 (1941) Satur	day:		
Mail order   Long-Term Care   Internet   Central Rx processing   Hospital     Mail order   Long-Term Care   Internet   Central Rx filling   □ Other (explain)     Nothing the following populations does the pharmacy serve? (Check all that apply.)     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy deliver into lowa last year?     Nothing the following accreditations does the pharmacy have? (Check all that apply.)     Nothing the following accreditations does the pharmacy have? (Check all that apply.)     Nothing the following the following pharmacy have? (Check all that apply.)     Nothing the following pharmacy deliver into lowa?     Nothing the following p		d)	have access to patient rec	ords at the time of the ca	all?		er hours of operation
Mail order   □ Long-Term Care   □ Internet   □ Central Rx filling   □ Other (explain)     Which of the following populations does the pharmacy serve? (Check all that apply.)   Sel-luman   Neterinary—companion animals   □ Veterinary—food-producing animals     9) Approximately how many prescriptions did the pharmacy deliver into lowa last year?     h) Which of the following accreditations does the pharmacy have? (Check all that apply.)   □ VPPS   □ VIPPS   NPCAB   □ ACHC   □ JCAHO   □ DMEPOS   □ Other   □ None     l) Does the pharmacy engage in compounding?   Nesterile High-Risk   Nesterile Medium-Risk   Nesterile Low-Risk   Non-sterile   □ Por office use by prescriber     □ For hospital use   □ For office use by prescriber     □ Does the pharmacy provide or intend to provide controlled substances to patients in lowa?   Yes   No (Nonresident pharmacies are required to report to lowa's Prescription   Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 lowa Administrative Code chapter 37 and the lowa Pata Reporting Manual.)   10 FDA INFORMATION:   No   No   No   No   No   No   No		•					
f) Which of the following populations does the pharmacy serve? (Check all that apply.)    Setuman   Neterinary—companion animals   Veterinary—food-producing english   Veterinary   Ves   No   None   None   None   None   None   Veterinary   None   None   Veterinary   Ves   No   None		- /	•		•	_	
Selhuman   Veterinary—companion animals   Veterinary—food-producing animals   Selhuman   Veterinary—companion animals   Veterinary—food-producing animals   Selhuman   Veterinary—companion animals   Veterinary—food-producing animals   Selhuman   Veterinary—food-producing into lowa   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   Veterinary—food-producing   None   None   Veterinary—food-producing   Veterinary—food-			· ·			9	, , ,
h) Which of the following accreditations does the pharmacy have? (Check all that apply.)    VPPS		(X)	Human Kveterinary	—companion animals	□ Veterinary—	-food-producin	g animals /
None		_					· ·
If yes, what types? (Check all that apply.)  Sterile High-Risk  Non-sterile  For hospital use  For hospital use  No (Nonresident pharmacies are required to report to lowa's Prescription Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 lowa Administrative Code chapter 37 and the lowa Data Reporting Manual.)  10 FDA INFORMATION:  a) Has the pharmacy ever been inspected by the FDA?  b) If yes, date of last inspection:  c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy?  response to the FDA.  d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility?  Yes  No  REMIT TO: IOWA BOARD OF PHARMACY  400 S.W. EIGHTH STREET, SUITE E  DES MOINES, IA 50309-4688  PHONE: (515) 281-5944  I hereby swear 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 the pharmacy license.							
Pursuant to patient-specific Rx		i) Þ	If yes, what types? (Check	all that apply.)			-Risk
For hospital use		•	-			> n anticipati	on of patient-specific Rx
Monitoring Program (PMP), including submission of zero reports. Please be aware of the reporting requirements described in 657 lowa Administrative Code chapter 37 and the lowa Data Reporting Manual.)  10 FDA INFORMATION:  a) Has the pharmacy ever been inspected by the FDA? Yes No  b) If yes, date of last inspection:  c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy? Yes No  If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.  d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? Yes No  REMIT TO: IOWA BOARD OF PHARMACY 400 S.W. EIGHTH STREET, SUITE Information provided in this application may be disclosed pursuant to 657 IAC chapter 14.  I hereby swear 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 the pharmacy license.			For hospital use	☐ For office use by p	rescriber	•	
a) Has the pharmacy ever been inspected by the FDA?YesNo  b) If yes, date of last inspection: c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy?Yes			Yes No Monitoring Program (PMF requirements described in C	(Nonresident pharm ), including submission	acies are requ of zero report	ired to report s. Please be	to Iowa's Prescription aware of the reporting Data Reporting Manual.)
b) If yes, date of last inspection:  c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy?YesNo   If yes, please attach the FDA documentation and include documentation regarding your pharmacy's   response to the FDA.  d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility?YesNo  REMIT TO: IOWA BOARD OF PHARMACY   400 S.W. EIGHTH STREET, SUITE E	10					٠, ,,	renwta5
c) If yes, has the FDA ever issued a 483 or a warning letter to the pharmacy?YesNo   If yes, please attach the FDA documentation and include documentation regarding your pharmacy's   response to the FDA.  d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility?YesNo  REMIT TO: IOWA BOARD OF PHARMACY   400 S.W. EIGHTH STREET, SUITE E					4? Yes	No	0
If yes, please attach the FDA documentation and include documentation regarding your pharmacy's response to the FDA.  d) Is the pharmacy registered with the FDA as a 503(b) outsourcing facility? Yes No  REMIT TO: IOWA BOARD OF PHARMACY		•					V V N-
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400 S.W. EIGHTH STREET, SUITE E DES MOINES, IA 50309-4688 PHONE: (515) 281-5944  I hereby swear 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 the pharmacy license.  11 SIGN HERE		d)	Is the pharmacy registered	with the FDA as a 503(	b) outsourcing f	acility?	Yes No
understand that failure to provide complete and truthful information may constitute grounds for denial, revocation, or other disciplinary sanctions against the pharmacy license.  11 SIGN HERE	RE	EMI <sup>-</sup>	400 S.W. EIGHTH S DES MOINES, IA 503	TREET, SUITE E 309-4688			
HERE PLANT THE THE THE THE THE THE THE THE THE TH	un	ders	tand that failure to provide c	omplete and truthful info	rmation may cor	n this applicationstitute grounds	on is true and correct. I for denial, revocation, or
<b>▼</b> リ	11						



### Ownership Disclosure:

1. Michael Pavlovich, PharmD President, Pharmacist-In-Charge

238 Savona Walk Long Beach, CA 90803

Licenses CA RPH42798 Exp 8/31/15 NV 10179 Exp 10/31/15 AZ Y005467 Exp 10/31/15 MD 21411 Exp 8/31/16

Interest 60%

2. John O'Connell, Pharm.D., MBA Secretary/Treasurer

3501 Kendell Hill Dr Santa Rosa, CA 95401

Licenses CA RPH38957 Exp 9/30/16

Interest 40%



### Staff Pharmacists:

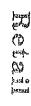
- 1. Michael Pavlovich, PharmD PIC CA Lic RPH42798 40+ hrs/wk
- 2. John O'Connell, Pharm.D., MBA CA Lic RPH38957 8 hrs/month
- 3. Theresa Do, Pharm.D. CA Lic RPH64293 8 hrs/wk



### Technicians:

- 1. Marisol Rivas CA TCH38614 40 hrs/wk
- 2. Jeyra Frias CA TCH64313 30 hrs/wk
- 3. Emilia Alcaraz CA TCH83397 38 hrs/wk





LICENSE

Z 0



1625 NORTH MARKET BLVD., SUITE N-219 SACRAMENTO, CA 95834 (916) 574-7900 BOARD OF PHARMACY .

中国

VALID UNTIL MARCH 01, 2016

RECEIPT WESTCLIFF COMPOUNDING PHARMACY 20 PHY 50599 50250754

02/09/15 02/09/15 The official status of this license can be verified at www.pharmacy.ca.gov

NON-TRANSFERABLE

**!** !

NEWPORT BEACH CA 92660

POST IN PUBLIC VIEW -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 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 administrator or pharmacist—in—charge.
This permit is valid only at the address shown. Pharmacy. (more than 10 percent share change)

FORM WPHPHY (12/31/05) PHY

WESTCLIFF COMPOUNDING PHARMACY 1901 WESTCLIFF DR #3 NEWPORT BEACH, CA 92660-0000-000

Rdankhlladkidladkirlladladladladladlad

DEA REGISTRATIO NUMBER	N THIS REGISTRATION EXPIRES	FEE PAID
FW2500432	05-31-2017	\$731
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	04-07-2014
1901 WESTCLI	DMPOUNDING PHARMACY FF DR #3A ACH, CA 92660-0000	
L		

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
FW2500432	05-31-2017	\$731
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	RETAIL PHARMACY	04-07-2014

WESTCLIFF COMPOUNDING PHARMACY 1901 WESTCLIFF DR #3A NEWPORT BEACH, CA 92660-0000

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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.

#### California State Board of Pharmacy 1625 N. Market Blvd, Suite 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.

### INSPECTION REPORT

Pharmacy	X Hospit	al Pharmacy	Clinic I	Exempt Hospital	Wholesa	ler H	ypodermic
Date:12	2/29/2014		Inspector: Anna	Yamada			ر زود در در در در المحالية المحالية المحالية المحالية المحالية المحالية المحالية المحالية المحالية ا
Firm: WES	TCLIFF COMPOU	INDING PHARMAG			· · · · · · · · · · · · · · · · · · ·		75
				City: NEWPORT		Zip: <u>92</u>	660
		,					
				DEA#: <u>FV</u>	V2500432	DEA Exp: _	5/31/2017
Date of Self A	Assessment Form:	6/30/2013	Other Permit #:	N/A	Date of DEA In	nventory:	5/1/2013
Hours M-F:	9AM-5:30PM		Hours Saturday	closed	I	Hours Sunday:	_closed
PIC MIC	HAEL A PAVLO	VICH RP	H42798	Administrator			
RPH Consul							
Staff RPH	Name:	I	icense #:	Staff N	lame:	Li	cense #;

#### Inspector Remarks:

Here today for follow-up inspection from Advance Outcome Management Pharmacy (PHY49946, AC 4682).

Advance Outcome pharmacy records (invoices, prescription, computer server) and dangerous devices (syringes and needles) were transferred to Westcliff Compounding Pharmacy on 12/24/14. Records and devices were boxed and sealed and stored in one of the pharmacy rooms. PIC Pavlovich was informed these items were no longer the property of Advance Outcome or Clarence Lloyd, and PIC Pavlovich wasnow responsible for these items.

Only a small number of dangerous drugs were transferred to pharmacy. Among the items were a couple of open containers of compounding ingredients and PIC Pavlovich was instructed to pull from active drug stock.

Licensee Remarks:

171-3 (10/02)

PHY50599

Page 1 of 2

1 NA

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

### INSPECTION REPORT

INSPECTION REPO	RT	1 1015
I have reviewed, discussed, understand and received a copy of this form.	Pharmacist (sign)	John Ah
1 2	Pharmacist (print)	MICHAEL PAVLOVIC
Inspector (sign)	Owner(sign)	
Inspector (print) Anna Yamada	Owner(print)	
Additional information (for example - corrective plan of action, Quality Assuration submit for consideration may be sent on the attached form to my attention at the date above. Please include a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with any information that you submit a copy of this form with a copy of this copy of this form with a copy of this cop	ie above addrece no later	n mitigation, etc.) you want to than 14 calendar days from the

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

171-3 (10/02)

PHY50599

Page 2 of 2

1 NA



California State Board of Pharmacy 1625 N. Market Blvd, Suite N219, Sacramento, & 95834 Phone (916) 5747900 Fax (916) 5748618 www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS GOVERNOR EDMUND G. BROWN JR.

### INSPECTION REPORT

Pha	rmacy X	Hospital Pharmacy	Clinic	Exempt Hospital	Wholesaler	Usmodows!.
Date	e: <u>4/3/2012</u>		Inspector: Jo			Hypodermic
		OMPOUNDING PHARM	ACY		Phone: (940) 2	72.0776
Addr	Address: 1901 WESTCLIFF DR #3A					p: 92660
Own	ership: <u>CORPOR</u>	A TION				p. <u>92000</u>
		Permit Exp:	3/1/2013		00432 DEA E	Sxp: 5/31/2014
		Form: 4/18/2011	Other Permit	0	ate of DEA Inventory	
Hours	M-F: <u>9am-5pn</u>	1	Hours Saturd	ay CLOSED		nday: <u>CLOSED</u>
PIC	MICHAEL A P	AVLOVICH F	PH42798		Martin Control of the	OBOOLD
RPH	Concultant					
Staff	RPH Name:		License #:	Staff Name	a•	License #:
SARAH M MICHAEL INT2					RIVAS	
H — H	Reference	· · · · · · · · · · · · · · · · · · ·				
i i	CFR 1305.22(g)	Procedures for filling ou Record must be electron	t electronic orders ically linked to the	(CSOS): Purchaser must re original order and archive	ecord quantity and dat	e received.
		1				
In that, the record of schedule II drugs received from Cardinal was not electonically archived and linked to the original order.						d and
С	c - Correctel					
2.	CCR 1707.5d	Interpretive Services to b	e available			
С		In that, policies and procavailable.	edures and a poste	ed notice for the provision o	f interpretive services	was not

California State Board of Pharmacy 1625 N. Market Blvd, Suite N2 19, Sacramento, & 95834 Phone (916) 5747900 Fax (916) 5748618 www.pharmacy.ca.gov

### INSPECTION REPORT

#### Inspector Remarks:

ROUTINE PHARMACY INSPECTION: Independent retail compounding pharmacy located adjacent to prescribers offices and retail shops. Pharmacy just recently opened on 3/28/2011.

- \*Patient consultation observed
- \*Quality Assurance Program: Incident report discussed with PIC
- \*CURES: reporting
- \*BOP e-mail notification subscription: helped pharmacy sign up
- \*Original Notice to Consumer posters displayed
- \*Original Pharmacy Permits posted
- \*Sink with hot and cold running water during inspection
- \*Refrigerator Temperature (USP 36-46F, 2-8C): 40F, temperature log in place
- \*Wholesalers: Cardinal (CSOS), API, Keysource
- \*Prescription Labeling has product description/ patient-centered

stained 1 prescription label Rx # 59203 (patient name redacted)

- \*Policies and Procedures: QA P+P·/ QA Review, TCH job duties, Temporary absence of RPH for lunch,
- \*Refill log: in place

Compounding: Pharmacy does nonsterile compounding

- -Compounding Self-Assessment: in place
- -Bulk Ingredient Invoices: in place, Letco, Medisca
- -Compounding logs: in place
- -Master formulas: in place
- -Balance/ Temperature log: in place
- -Compounding p/p: in place
- -Compounding QA/ end product testing: ARL
- -Labeling: reviewed

#### DISCUSSION:

- 1. Theft/Impairment policy and procedures: revise to include mental and physical impairment.
- 2. Discussed about requirements of Initial DEA Inventory.

In order to complete inspection, PIC to send Inspector Lee via e-mail or fax the following (Email: Joshua.lee@dca.ca..gov, Fax: (858) 618-1794):

CRECTIONS:

California State Board of Pharmacy 1625 N. Market Blvd, Suite N219, Sacramento, Ø 95834 Phone (916) 5747900 Fax (916) 5748618 www.pharmacy.ca.gov

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

### INSPECTION REPORT

1. The record of schedule II drugs received from Cardinal was not electonica statement of correction within 30 days.	ally archived and linked to the original order. Send
2. Policies and procedures and a posted notice for the provision of interpretive	ve services was not available. Send copy within 30 days
Licensee Remarks:	1, On On
have reviewed, discussed, understand and received a copy of this form.	Pharmacist (sign)
	Pharmacist (print) 1144EL PAWOVI
Inspector (sign)	Owner(sign)
Inspector (print) 103hr 2 CPO	Owner(print)
Additional information (for example - corrective plan of action, Quality Assurable submit for consideration may be sent on the attached form to my attention at the date above. Please include a copy of this form with any information that you set above.	the obove address we let all the time
Within 14 calendar days from the above date, please submit to me at the above	



Description of Prescription Drugs and Services Provided to Iowa Patients

We have developed a line of implantable medications and a tight delivery system whereby orders are placed directly to the pharmacy by way of an electronic prescription connection. The following are intended for shipment to lowa patients and/or their physicians:

Estradiol
Naltrexone
Oxytocin
Progesterone
Testosterone/DHEA
Testosterone/Povidone

This list is not exclusive and may change upon new research and physician request.

Pellets are compounded in a ISO Class 7 cleanroom within an ISO Class 5 BioSafety Cabinet and ultimately sterilized by way of electron beam process. Batches are routinely tested for sterility and potency. The process has been validated by FDA on multiple occasions in the innovator's pharmacy.

## the DataBank

P.O. Box 10832 Chantilly, VA 20153-0832

http://www.npdb.hrsa.gov

DCN: 5500000085593545 Process Date: 11/05/2013

Page: 1 of

WESTCLIFF COMPOUNDING PHARMACY

For authorized use by:

WESTCLIFF COMPOUNDING PHARMACY

### WESTCLIFF COMPOUNDING PHARMACY

### COLORADO STATE BOARD OF PHARMACY

### STATE LICENSURE ACTION

Initial Action

Date of Action: 11/04/2013

Basis for Initial Action

- PUBLICLY AVAILABLE FINE/MONETARY PENALTY

- OPERATING BEYOND SCOPE OF LICENSE

A. REPORTING **ENTITY** 

Entity Name: COLORADO STATE BOARD OF PHARMACY

Address: 1560 BROADWAY, STE. 1300

City, State, Zip: DENVER, CO 80202-0546

Country:

Name of Office: COLORADO STATE BOARD OF PHARMACY

Title or Department: DORA/PROGRAM DIRECTOR

Telephone: (303) 894-7754

Entity Internal Report Reference:

Type of Report: INITIAL

**B. SUBJECT** 

IDENTIFICATION INFORMATION (ORGANIZATION)

Organization Name: WESTCLIFF COMPOUNDING PHARMACY

Other Organization Name(s) Used:

Business Address: 1901 WESTCLIFF DR

STE 3A

City, State, ZIP: NEWPORT BEACH, CA 92660

Organization Type: PHARMACY (345)

Names and Titles of Principal Officers and Owners (POO):

Federal Employer Identification Numbers (FEIN): 900599689

Social Security Numbers (SSN):

Individual Taxpayer Identification Numbers (ITIN):

State License Number, State of Licensure: OSP.0005969, CO

Is the Subject a health care entity that provides health care services and engages in a formal peer review process for the

purpose of furthering quality health care?:

Drug Enforcement Administration (DEA) Numbers:

Clinical Laboratory Act (CLIA) Numbers:

Food and Drug Administration (FDA) Numbers:

National Provider Identifiers (NPI):

Medicare Provider/Supplier Numbers:

Name(s) of Health Care Entity (Entities) With Which Subject Is

Affiliated or Associated (Inclusion Does Not Imply Complicity in

the Reported Action.):

Business Address of Affiliate: City, State, ZIP:

Nature of Relationship(s):

C. INFORMATION REPORTED

Type of Adverse Action: STATE LICENSURE

Basis for Action: OPERATING BEYOND SCOPE OF LICENSE (AF)

Name of Agency or Program That Took the Adverse Action

Specified in This Report:

COLORADO STATE BOARD OF PHARMACY

Adverse Action

CONFIDENTIAL DOCUMENT - FOR AUTHORIZED USE ONLY

# the DataBank

P.O. Box 10832 Chantilly, VA 20153-0832

http://www.npdb.hrsa.gov

**DCN:** 5500000085593545 Process Date: 11/05/2013

Page: 2 of

WESTCLIFF COMPOUNDING PHARMACY

For authorized use by:

WESTCLIFF COMPOUNDING PHARMACY

74:			
Description of Su	Classification Code(s):     Date Action Was Taken:     Date Action Became Effective:     Total Amount of Monetary Penalty,     Assessment and/or Restitution:     Subject Automatically Reinstated After     Adverse Action Period Is Completed?:     ibject's Act(s) or Omission(s) or Other     en and Description of Action(s) Taken	11/04/2013 \$ 6,600.00 STIPULATION AND FINAL AGENCY ORDER, DI	STRIBUTED 909
[	Subject identified in Section B ha	PRESCRIPTION DRUGS INTO COLORADO WITHOUT ORDERS. PLEASE REFER TO BOARD DOCUMENT INFORMATION.  s appealed the reported adverse action.	OUT PRESCRIPTION PORT OF THE PROPERTY OF THE P
		(	
D. SUBJECT STATEMENT	If the subject identified in Section B o	f this report has submitted a statement, it appears in	this section.
REPORT STATUS	Unless a box below is checked, the si	ubject of this report identified in Section B has not co	placted this report
		appose of this topole identified in Section B flas flot of	ntested this report.
	If box is checked, at the request Secretary of the U.S. Departmen	s been disputed by the subject identified in Section B of the subject identified in Section B, this report is bo nt of Health and Human Services to determine its ac g requirements. No decision has been reached.	eing reviewed by the
	If box is checked, at the request the Secretary of the U.S. Depart is shown below:	of the subject identified in Section B, this report was ment of Health and Human Services. The Secretary	reviewed by s decision
NATIONAL AND	Date of Original Submission: Date of Most Recent Change:	11/05/2013 11/05/2013	
The information contained provisions of Section 1921 he purpose for which it wa	as disclosed. Disclosure or use of coordinates or clarification, contact the reporting	National Practitioner Data Bank for restricted us CFR Part 60. All information is confidential and onfidential information for other purposes is a v g entity identified in Section A.	may be used only for
	END	OF REPORT ———————	
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