IOWA WHOLESALE DISTRIBUTOR RENEWAL APPLICATION INSTRUCTIONS

To be used for license renewal only. Changes to name, address, ownership, and facility manager are not permitted when renewing your license.

Every wholesaler as defined in rule 657—17.3(155A) that engages in wholesale distribution into, out of, or within this state must be licensed by the Board before engaging in wholesale distribution. Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be separately licensed. The applicant shall submit a completed application for each location with a nonrefundable application fee of $750 plus a nonrefundable fee of $45 for completion of a criminal history background check on the facility manager. A Wholesale Distributor license expires annually on December 31.

Only information relating to the applicant-facility should be provided in this application. Do not include information or responses relating to another facility/location.

CONTROLLED SUBSTANCES -- EVERY wholesale distributor that engages in or intends to engage in wholesale distribution of controlled substances into, out of, or within this state must also be registered pursuant to the Iowa Controlled Substances Act (CSA) and 657—Chapter 10 before engaging in wholesale distribution of controlled substances. If you do not currently have a CSA registration and are engaged in wholesale distribution of controlled substances into, out of, or within Iowa, you must apply for registration by checking the box in section 9 of this application and include an additional $90 non-refundable CSA registration application fee for each activity indicated in section 9.

Accreditation Requirement– Applicants must provide evidence of current Drug Distributor Accreditation (DDA-formally known as VAWD) accreditation by the National Association of Boards of Pharmacy, QAS accreditation by the National Coalition for Drug Quality and Security (NCDQS), another accreditation body approved by the Board, or compliance with a Iowa Board of Pharmacy-approved waiver.

*** Instate location ***
The accreditation requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a Board compliance officer or agent of the Board prior to issuance of an initial license. However, licensees must provide evidence of compliance with the accreditation requirement on or before the initial renewal of the license.

Submit the completed application, including the checklists, all attachments, and a check/money order in the appropriate amount made payable to:

Iowa Board of Pharmacy
6200 Park Ave. Ste. 100
Des Moines, IA 50321

Name/Address/Ownership Change and Facility Manager Change – Changes made to the name, ownership, and/or location **cannot** be made on a renewal application and require the submission of a separate completed change application and applicable fee(s). Multiple changes to a license within the same application require only a single fee for the license and each registration. A change of facility manager

cannot be made on a renewal application and requires the submission of a separate completed Facility Manager Change application and applicable fee(s).

FOR ALL APPLICANTS: Board staff will process applications in the order received. A completed application will be reviewed and processed within 10 business days of receipt. The applicant will be notified via email regarding any missing information. An incomplete application for a wholesale distributor license will be maintained for a maximum period of 6 months. Failure to submit all required information within 6 months of submission of the original application will result in the application becoming null and void.

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

Renewal Application Fees	
Renewal Application Fee (November 1-December 31)	$750.00
Renewal Controlled Substance Act - Business(CSA-B) Registration Fee (if applicable, per registration)	$90.00
A wholesale distributor that handles controlled substances is required to obtain a CSA-B registration and submit a $90.00 fee for each independent activity indicated in section 9 of the application.	
Late License Application Fees – These fees are due for applications that are not timely submitted, but are submitted within 30 days of the required submission period	
Wholesale Distributor Application and Penalty Fee (January 1 – January 31)	$1500.00
CSA-B Registration and Penalty Fee (if applicable, per delinquent registration)	$180.00
Reactivation Fees – The following fees are due for applications submitted more than 30 days after required submission period.	
Wholesale Distributor Reactivation Fee	$2000.00
CSA-B Registration Reactivation Fee (if applicable, per expired registration)	$360.00

APPLICATION CHECKLIST	
Most Recent Inspection Report	**☐YES ☐NO**
Proof of NABP DDA, QAS, Board Approved Accreditation, or compliance with Board approved waiver	**☐YES ☐NO**
Most recent FDA Inspection Report, FDA 483s, Warning Letters, and Responses, if not previously provided to the Board	**☐YES ☐N/A**
Copy of License/Permit from State of Residence if outside Iowa	**☐YES ☐NO**
Surety Bond (or equivalent means of security) and Proof of Annual Gross Receipts for prior tax year (if claiming $10 million or less A government-owned wholesale distributor is exempt from the surety bond and prior tax year gross receipts requirements.	**☐YES ☐NO**
List of each criminal conviction and court records of the conviction(s) not previously reported to the Board	**☐YES ☐N/A**
List of disciplinary actions by any licensing authority and documentation of final disciplinary orders not previously reported to the Board	**☐YES ☐N/A**
List of final denial orders by any licensing authority and documentation of final denial orders not previously reported to the Board	**☐YES ☐NA**
CONTROLLED SUBSTANCE REGISTRATION ACT CHECKLIST	
Copy of DEA Certificate (if applicable)	**☐YES ☐N/A**

IOWA WHOLESALE DISTRIBUTOR LICENSE RENEWAL APPLICATION

To be used for license renewal only. Changes to name, address, ownership, and facility manager are not permitted when renewing your license.

Please type or print legibly in ink.

1. FACILITY TYPE:	
Wholesale Distribution – Human Drugs ☐	**Reverse Distributor** ☐

If your business type does not fall into one of these two types this is not the correct license or application.

2. APPLICANT/LICENSEE INFORMATION:			
Business Name ***(name in which company is doing business)*****:**			
Legal Name ***(if different)*****:**		**Iowa License Number:**	
Federal Tax ID#:		**NABP e-profile ID #:**	
If the facility does not have an NABP e-profile number, you may create one by going to nabp.pharmacy			
TYPE OF OWNERSHIP ***(check all that apply)*****:**			
Sole Proprietorship ☐	**Partnership** ☐	**C Corporation** ☐	
S Corporation ☐	**LLC** ☐	**Government** ☐	
FACILITY ADDRESS ***(physical location of establishment which should be reflected on all sales invoices and shipping documents)*****:**			
Street Address:			
Address:		**Suite:**	
City:	**State:**	**Zip:**	

Note: The facility phone number must be a direct number to the licensed facility

Phone #:		**Extension:**	
Landline: ☐ **Yes** ☐ **No**		**Cell Phone (text messages):** ☐ **Yes** ☐ **No**	
Alternate Phone #:		**Extension:**	
Landline: ☐ **Yes** ☐ **No**		**Cell Phone (text messages):** ☐ **Yes** ☐ **No**	
Fax #:			
Note: This must be an email that is regularly reviewed by the licensee – Board communications to the facility will initiate via this email. Email address of a license servicing agency is not acceptable – this address must deliver directly to the licensee or the licensee's facility manager.			
Email Address:			
Web site:			
MAILING ADDRESS ***(where all correspondence regarding licensure will be sent if other than facility address)*****:**			
Address:		**Suite #:**	
City:	**State:**	**Zip:**	

3. OWNERSHIP ***(an ownership change occurs when the owner listed on the wholesale distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the wholesale distributor's most recent application)*****:**	
Name of Legal Owner:	
Address of Legal	

Owner:					
City:		**State:**		**Zip:**	
Owner Phone #:		**Extension:**			
Fax:		**Email Address:**			
Date Established:		**State of Incorporation:**			

4. OPERATIONS

STATE AND FEDERAL PERMIT/LICENSE/REGISTRATION NUMBERS ***(attach additional pages if necessary)*****:**

Licensing Body:	Permit/License/Registration #:	Issue Date:	Expiration Date:	Status:

HOURS OF OPERATION: ***(indicate opening and closing times each day; indicate "closed" if not open any day)***

Sunday:		**Monday:**	
Tuesday:		**Wednesday:**	
Thursday:		**Friday:**	
Saturday:			

CUSTOMERS: ***(select all that apply)***

Other Wholesale Distributors ☐	**Hospitals** ☐	**Pharmacies** ☐
Practitioners (Human) ☐	**Patients/End Users** ☐	**Other:**

PRODUCTS DISTRIBUTED: ***(select all that apply)***

DRUGS:	**Human Prescription Drugs** ☐
Human Nonprescription Drugs ☐	**Human Controlled Substances** ☐
Veterinary – Companion Animal Prescription Drugs ☐	**Veterinary – Companion Animal Nonprescription Drugs** ☐
Veterinary – Companion Animal Controlled Substances ☐	**Veterinary – Food Producing Animal Prescription Drugs** ☐
Veterinary – Food Producing Animal Nonprescription Drugs ☐	**Veterinary – Food Producing Animal Controlled Substances** ☐
DEVICES/GASES/OTHER:	
Prescription/Patient-Use Devices ☐	**Prescription/Professional-Use Devices** ☐
Nonprescription Devices ☐	**Medical Gases** ☐
Other ***(please explain)*****:**	

5. ACCREDITATIONS. *At least one of the first four boxes must be checked by every applicant..*

☐ **1. NABP - DDA**	☐ **2. NCDQS - QAS**	☐ **3. BOARD-APPROVED WAIVER**
☐ **4. OTHER BOARD-APPROVED ACCREDITATION (specify)**	☐ **DMEPOS**	☐ **ACHC**
☐ **OTHER: (specify)**	☐ **CHAP**	☐ **JOINT COMMISSION**

6. INSPECTION INFORMATION:

Since your last application, has the facility been inspected by the FDA:	☐ **YES** ☐ **NO**
If yes, date of most recent FDA inspection:	

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**
Has this facility ever been inspected by a state licensing authority or other third-party (*attach the most recent Inspection Report*)?	☐ **YES** ☐ **NO**
If yes, date of most recent inspection:	
Most Recent Inspection Performed by:	
Are you registered with the FDA as a 503(b) outsourcing facility?	☐ **YES** ☐ **NO**

7. REGISTERED AGENT ***(– All applicants must have a Registered Agent that is physically located in Iowa. In the event that legal documents or correspondences must be served, they will be served to your Registered Agent.)***

Name of Registered Agent:					
Business Address:				**Suite #:**	
City:		**State:**		**Zip:**	

8. SURETY BOND - Proof of a surety bond or other security of equal value must be submitted by all applicants who are engaged in wholesale distribution as defined by the federal Drug Supply Chain Security Act. The bond shall be in the amount of $100,000, unless the applicant's annual gross receipts in Iowa from the previous tax year are less than $10,000,000, in which case the bond shall be in the amount of $25,000. If submitting a $25,000 bond, proof of prior tax year gross receipts in Iowa must be provided.

Is a surety bond or other equivalent means of security attached?	☐ **YES** ☐ **NO**
Annual gross receipts in Iowa for previous tax year are less than $10,000,000 (please attach appropriate documentation) ☐ **YES** ☐ **NO**	
Annual gross receipts in Iowa for previous tax year are $10,000,000 or more ☐ **YES** ☐ **NO**	

9. CONTROLLED SUBSTANCES - A Controlled Substances Act-Business Registration is required for each activity involving the handling of controlled substances into, out of, or within Iowa. If you currently hold one or more CSA-B registrations and the registrations are not scheduled for renewal, do not submit the CSA-B renewal fee.

New CSA-B Registration(s) ***(check the box if you wish to apply)***			
DEA Registration #:		**Expiration Date:**	
FDA # :		**Expiration Date:**	
IA CSA-B Registration #:		**Expiration Date:**	
BUSINESS TYPE (*a separate CSA-B registration and $90 fee is required for each activity checked below)*:			
Manufacturer ☐	**Analytical Lab** ☐	**Distributor/Reverse Distributor** ☐	
Importer/Exporter ☐	**Researcher – Business** ☐	**Outsourcing Facility** ☐	

DISTRIBUTION ***(check all schedules of controlled substances that distribute or otherwise handle within or into Iowa)*:**

Schedule I (research or analytical lab only) ☐	**Schedule II Narcotic** ☐	
Schedule II Nonnarcotic ☐	**Schedule III Narcotic** ☐	
Schedule III Nonnarcotic ☐	**Schedule IV** ☐	**Schedule V** ☐

RESPONSIBLE INDIVIDUAL ***(whose signature is authorized on Federal Controlled Substances Order Form 222 or CSOS)***

Name:		**Title:**			
Social Security Number:		**Date of Birth:(*mm/dd/yyyy*)**			
Address:		**State:**		**Zip:**	
Primary Phone #:			**Extension:**		
Email Address:					

LOST OR STOLEN CONTROLLED SUBSTANCES:					
During the past two years have any controlled substances under your control or ownership been lost or stolen? If yes, indicate the number of incidents next to the applicable reason(s).		☐ YES ☐ NO			
Break-In:		**Armed Robbery:**		**Employee Pilferage:**	
Customer Theft:		**Lost in Transit:**		**Other: (specify)**	

As the responsible individual, I, _____, attest that I have adequate experience in prescription drug distribution. I have and will maintain a functional understanding of federal and state laws, rules, and regulations pertaining to drug distribution, as applicable.

I hereby swear or affirm that I, _____, have no felony convictions or convictions related to prescription drug and device distribution including distribution of controlled substances except those that may have been disclosed on this or previous applications to the Board. .

Signature:	
Date:	

10. FACILITY MANAGER – the facility manager is the individual responsible for the day-to-day operations of the wholesale distributor *(provide full legal name)*					
First Name:					
Middle Name:		**Last Name:**			
Previous Name(s) Used					
Street Address:					
City:		**State:**		**Zip:**	
Phone #:		**Extension:**			
Landline:	☐ Yes ☐ No	**Cell Phone (will accept text message):**	☐ Yes ☐ No		
Alternate Phone #:		**Extension:**			
Landline:	☐ Yes ☐ No	**Cell Phone (will accept text message):**	☐ Yes ☐ No		
Email:					
Date of Birth:		**Social Security Number:**			
Date started as Facility Manager at this location:					

As Facility Manager, I, _____, attest that I have adequate experience in prescription drug and device distribution, as applicable, and am actively involved in the daily operation of this distribution facility. I have and will maintain a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution, as applicable.

I hereby swear or affirm that I, _____, have no felony convictions or convictions related to prescription drug and device distribution including distribution of controlled substances except those that may have been disclosed on this or previous applications to the Board.

Signature:	
Date:	

11. CRIMINAL HISTORY

A. Since the last application have any of the applicant(s), owners, and/or facility manager been convicted of, or entered a plea of guilty, nolo-contendere, or no contest to a crime, other than a minor traffic offense, 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. (For example, you must report if your conviction was expunged, you received a deferred judgment, or received an executive pardon.)

☐ YES ☐ NO

B. Include a separate sheet of paper providing a signed and dated explanation of each conviction and attach court records of the conviction(s). For applicant, do not include criminal records relating to another facility or location. Only include records and information for crimes relating to operations, activities, and licenses/registrations at this facility.

Attachment included:	☐ YES ☐ NO

12. DISCIPLINARY ACTIONS

A. Since the last application has the applicant, or any owner, officer, partner, or facility manager 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

B. Include a separate sheet of paper listing all disciplinary actions by any licensing authority and include documentation of any final disciplinary order. For applicant, do not include discipline relating to another facility or location. Only include records and information for discipline relating to operations, activities, and licenses/registrations at this facility.

Attachment included:	☐ YES ☐ NO

C. Since the last application has the applicant been denied a license by any licensing authority?

☐ YES ☐ NO

D. Include a separate sheet listing the final denial orders by any licensing authority and include documentation of any final denial orders.

Attachment included:	☐ YES ☐ NO

E. Do you have any knowledge of any investigations, complaints, or charges pending before any licensing authority?

☐ YES ☐ NO

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

Attachment included:	☐ YES ☐ NO

13. 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 this license.

Signature of Applicant:			
Date:			
Printed Name and Title:			
Business Telephone #:		**Business Fax #:**	