



Iowa Board of Pharmacy

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

Petition for Waiver Form

Please review the Board's rules governing waivers and variances in 657 IAC chapter 34 prior to filing a petition for waiver. Complete this form and submit it, including supporting documentation, to the Board by mail or email to Amanda.woltz@iowa.gov. Deadline for inclusion on the Board's agenda is two weeks prior to a Board meeting.

Licensee/Registrant Name: HUB Pharmaceuticals, LLC

License/Registration No.: 8207

Street Address: 800 Junction Street, Dock #1

City: Plymouth State: MI Zip Code: 48170

Contact Person for Petition for Waiver: Jerry Rosenstein

Phone Number: 951-833-5400 Email: orders@hubrx.com

List each rule you are requesting to be waived:

VAWD Accreditation requirement for Wholesale Distribution - Human Drugs License

Describe specifically which requirements you are requesting to be waived:

VAWD Accreditation requirement for Wholesale Distribution - Human Drugs License. Please accept the NCDQS Accreditation in lieu of VAWD Accreditation. We expect to receive NCDQS Accreditation within the next 3 months.

List the time period for which you are seeking a waiver. The start date must be a future date. An end date must be requested.

Start date: March 31, 2020

End date: May 31, 2020

Have you previously requested a waiver of any of the rules listed above? If so, what was the outcome? If a prior petition for waiver was granted, attach a copy of Board's prior written ruling or correspondence.

NO

For each rule you are requesting to be waived, provide the following explanations:

1. Explain why following the rule would pose an undue hardship:
2. Explain how waiving the rule may impact other people:
3. Explain how the rule is intended to protect the public health, safety, or welfare:
4. Explain how the public health, safety, or welfare can still be protected if the rule is waived:

Have you spoken to a Board compliance officer or other member of Board staff about your request? If so, who?
Attach copies of any relevant email correspondence. Yes No

Do you plan to attend the Board meeting when this Petition will be considered? Yes No

Attach any relevant documentation to support your answers.

I hereby attest to the accuracy and truthfulness of the information contained herein.

Signature:  _____

Date: 2/19/20

Printed Name: Jerry Rosenstein

Title: President

1. Explain why following the rule would pose an undue hardship:

We have been committed to earning VAWD Accreditation since before the Iowa Board of Pharmacy announced the requirement (January 2018); however, given the VAWD program's extremely long processing times, we potentially may not earn VAWD accreditation by the Iowa deadline.

2. Explain how waiving the rule may impact other people:

We do not believe waiving this rule will impact other people.

3. Explain how the rule is intended to protect the public health, safety, or welfare:

VAWD Accreditation is widely regarded as the "gold-standard" for drug distribution/supply chain.

4. Explain how the public health, safety, or welfare can still be protected if the rule is waived:

We are committed to operating not only in compliance with Federal and State regulations but is committed to embracing industry best practices. We believe NCDQS Accreditation is a comparable program in promoting the quality and security of the US drug supply chain. If the Iowa Board of Pharmacy would temporarily waive this rule and accept NCDQS Accreditation in lieu of VAWD Accreditation until we earn VAWD Accreditation, we believe the public health, safety, or welfare will still be protected.

IOWA BOARD OF PHARMACY
400 S.W. EIGHTH STREET, SUITE E
DES MOINES, IA 50309-4688
515/281-5944 FAX 515/281-4609
<https://pharmacy.iowa.gov>

2020

Wholesale Distributor License No. 8207

ISSUED 03/29/2019

EXPIRES 03/31/2020

MUST BE CONSPICUOUSLY DISPLAYED IN LOCATION TO WHICH IT APPLIES

MAILING ADDRESS

HUB Pharmaceuticals LLC
800 Junction St Dock 1
Plymouth MI 48170

LICENSED LOCATION

HUB Pharmaceuticals LLC
800 Junction St Dock 1
Plymouth MI 48170

Ryan Andrew Shippe , Facility Manager

**Invitation: NCDQS Virtual Site-Survey / Hub Rx - Plymouth, MI @ Fri Jul 24, 2020
9am - 3pm (EDT) (chris@hubrx.com)**

info@ncdqs.org <info@ncdqs.org>

Tue 5/26/2020 9:33 AM

To: Chris McKee <chris@hubrx.com>; Stuart Green <stuart@diagnosticgreen.com>; denise@ncdqs.org <denise@ncdqs.org>; Mary Griffin <MGriffin@hubrx.com>; Joel Lindblade <joel@hubrx.com>

📎 1 attachments (3 KB)

invite.ics;

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

You have been invited to the following event.

NCDQS Virtual Site-Survey / Hub Rx - Plymouth, MI

When Fri Jul 24, 2020 9am – 3pm Eastern Time - New York

[more details »](#)

Where FaceTime (preferred) or Zoom ([map](#))

Calendar chris@hubrx.com

Who

- info@ncdqs.org - organizer
- chris@hubrx.com
- stuart@diagnosticgreen.com
- denise@ncdqs.org
- mgriffin@hubrx.com
- joel@hubrx.com

Agenda:

1. Connect via FaceTime (preferred) or Zoom
2. Introductions
3. Surveyor reviews agenda
4. Recap of business model by facility staff
5. Surveyor requests specific documents to be provided electronically to NCDQS
6. Surveyor requests documents to be viewed
7. Surveyor tour of facility

Zoom Information:

National Coalition for Drug Quality & Security is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://us02web.zoom.us/j/85940843676>

Meeting ID: 859 4084 3676

One tap mobile
+16699006833,,85940843676# US (San Jose)
+12532158782,,85940843676# US (Tacoma)

Dial by your location
+1 669 900 6833 US (San Jose)
+1 253 215 8782 US (Tacoma)
+1 346 248 7799 US (Houston)
+1 301 715 8592 US (Germantown)
+1 312 626 6799 US (Chicago)
+1 929 205 6099 US (New York)
Meeting ID: 859 4084 3676
Find your local number: <https://us02web.zoom.us/j/85940843676>

Going (chris@hubrx.com)? [Yes](#) - [Maybe](#) - [No](#) [more options »](#)

Invitation from [Google Calendar](#)

You are receiving this courtesy email at the account chris@hubrx.com because you are an attendee of this event.

To stop receiving future updates for this event, decline this event. Alternatively you can sign up for a Google account at <https://www.google.com/calendar/> and control your notification settings for your entire calendar.

Forwarding this invitation could allow any recipient to send a response to the organizer and be added to the guest list, or invite others regardless of their own invitation status, or to modify your RSVP. [Learn More](#).

HUB Pharmaceuticals NCDQS Audit 24JUL2020

National Coalition of Drug Quality & Security <info@ncdqs.org>

Fri 5/29/2020 11:00 AM

To: Stuart Green <stuart@diagnosticgreen.com>

Cc: Joel Lindblade <joel@hubrx.com>; Mary Griffin <MGriffin@hubrx.com>; Chris McKee <chris@hubrx.com>; Jerry Rosenstein <DrJerry@hubrx.com>; Denise Frank <denise@ncdqs.org>

[EXTERNAL EMAIL] DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe.

Mr. Green,

I apologize for the misunderstanding - I believe there was a formatting issue in the invitation. Below is a better formatted version, as there should not have been any blanks (there are only 7 agenda items). As far as an audit plan, Denise will advise next week.

1. Connect via FaceTime (preferred) or Zoom
2. Introductions
3. Surveyor reviews agenda
4. Recap of business model by facility staff
5. Surveyor requests specific documents to be provided electronically to NCDQS
6. Surveyor requests documents to be viewed
7. Surveyor tour of facility

Please let me know if you have any questions or concerns. Thank you!



Office Coordinator
National Coalition for Drug Quality & Security
info@ncdqs.org
(844) 80-NCDQS [(844) 806-2377]

----- Forwarded message -----

From: **Stuart Green** <stuart@diagnosticgreen.com>

Date: Tue, May 26, 2020 at 12:49 PM

Subject: HUB Pharmaceuticals NCDQS Audit 24JUL2020

To: denise@ncdqs.org <denise@ncdqs.org>

Cc: Joel Lindblade <joel@hubrx.com>, Mary Griffin <MGriffin@hubrx.com>, Chris McKee <chris@hubrx.com>, Jerry Rosenstein <DrJerry@hubrx.com>

Hello Denise,

The HUB Pharmaceuticals team is looking forward to the NCDQS audit 24JUL2020 and in preparation we would like to further our gap analysis. The agenda attached to the invitation is shown below but we were wondering if you have a specific audit plan to which we can align in an attempt to close any gaps prior to the audit. In our view this will help to facilitate a smoother inspection and ensure we are moving towards compliance as quickly as possible.

Note there were a points below (2, 5, 10) without details so we were wondering if you could fill in the blanks.

Agenda:

1. Connect via FaceTime (preferred) or Zoom
- 2.
3. Introductions
4. Surveyor reviews agenda
- 5.
6. Recap of business model by facility staff
7. Surveyor requests specific documents to be provided electronically to NCDQS
8. Surveyor requests documents to be viewed
9. Surveyor tour of facility
- 10.

Best Regards,

-Stu

Stuart Green

Executive VP Global Compliance & Pharmaceutical MFG

Diagnostic Green LLC

38955 Hills Tech Drive

Farmington Hills, MI 48331

Mobile: 1-570-249-0112

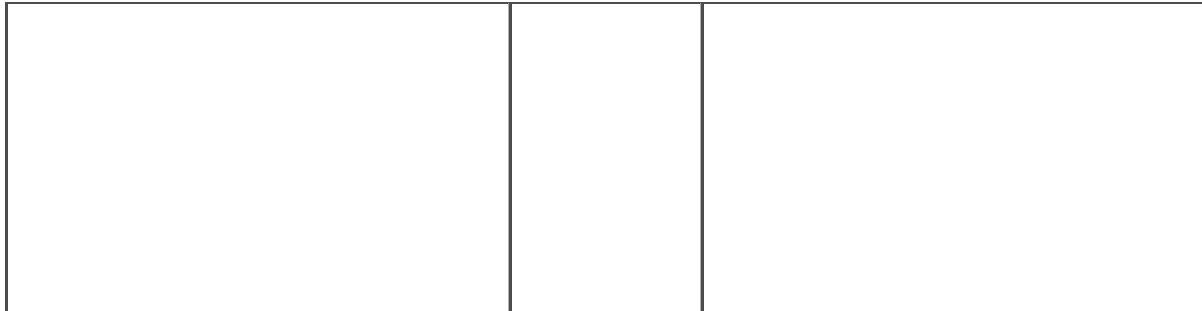
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Your NATIONAL COALITION FOR DRUG QUALITY & SECURITY DENISE M FRANK MBR receipt [#1342-8967]

NATIONAL COALITION FOR DRUG QUALITY & SECURITY DENISE M FRANK MBR
<receipts+acct_1FJo5cHAW02aU88A@stripe.com>

Fri 2/7/2020 10:55 AM

To: Chris McKee <chris@hubrx.com>



Receipt from NATIONAL COALITION FOR
DRUG QUALITY & SECURITY DENISE M
FRANK MBR

Receipt #1342-8967

AMOUNT PAID	DATE PAID	PAYMENT METHOD
\$5,000	February 7, 2020	Mastercard – 0896

SUMMARY

Accreditation Organization	\$5,000.00
Amount paid	\$5,000.00

If you have any questions, contact us at info@ncdqs.org or call at +1 844-806-2377.

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