Incomplete till 2023 under construction

Make Check Payable To:
Treasurer, State of NH
Application Fee: $500
Reinstatement is additional $25.00

State of New Hampshire
Board of Pharmacy
7 Eagle Square, Suite 300
Concord, NH 03301
Tel (603) 271-2350 Fax (603) 271-2856
www.oplc.nh.gov/pharmacy

RECEIVED
SEP 22 2022
BY: #500 √ #648927

APPLICATION FOR MANUFACTURER, WHOLESALER, BROKER, REPACKER, RELABELER OR DISTRIBUTOR OF PRESCRIPTION DRUGS OR DEVICES FOR SALE OR DISTRIBUTION IN NEW HAMPSHIRE AT WHOLESALE (NOT TO THE END PATIENT)

(NOT FOR USE TO APPLY FOR A BULK COMPOUNDING / 503B OUTSOURCING PERMIT)

Location Of Facility Where Actual Manufacturing / Distribution Takes Place (If Broker Only, Business Mailing Address):

Company Name: Amgen Inc.

Street Address: 4150 Ganton Parkway

City / State / Zip: New Albany, Ohio, 43054

Parent Company (If none, write 'None'): Amgen Inc.

State Of Incorporation (If Corp.): DE

Provide the name, title, & business mailing address of the person to whom the permit, future renewal applications, and all Board communications should be directed:

Name:	Title:	Tel. #:
Susan Simons	Sr. Manager Regulatory Affairs	805-447-1000

Mailing Address:
ATTN: State Licensing, One Amgen Center Drive, Thousand Oaks, CA 91320

E-Mail Address (Must Be Entered to Receive Your NH License):
statelicensing@amgen.com

Nature of Business: (Check one) - *Note: Bulk Non-Sterile & Sterile Compounding / Outsourcing / FDA 503B Facilities Cannot Be Licensed as Manufacturers or Wholesalers in NH*:

☑ **Manufacturer** * *If checked, is your company currently licensed by the FDA?* ☐ Yes ☑ No ☐ **Virtual Manufacturer**
Current FEI number: 3020740318 Registration with FDA in process
Current DUNS: 118378297

☐ **Wholesaler/Distributor** ☐ **Broker/Reseller** ☐ **Relabeler/Repackager** ☐ **Virtual Distributor**

☐ **3PL (Third Party Logistics) Provider** (licensure required only if Rx products are physically warehoused/stored in the 3PL's own warehouse/distribution center prior to shipping)

☐ **Reverse Distributor** ☐ **Other** (please describe activity):

DEA Number (If Shipping Controlled Drugs):	Home State Controlled Substance Lic. #, If Applicable:
N/A Amgen does not store, distribute, or manufacture controlled substances. No DEA number is assigned.	N/A

Is the above referenced company (physical location) licensed by the state licensing authority or board of pharmacy in the state of location?	☑ **Yes** ☐ **No** * ** If 'No', you must attach an explanation.*
Within the last 3-years, has a registration or licensure granted to the above referenced company by any state or federal agency been suspended, revoked, or otherwise disciplined?	☐ **Yes** * ☑ **No** ** If "Yes", attach a detailed explanation, along with copy of legal documentation noting discipline.*

APPLICATION CONTINUED ON NEXT PAGE

Name of Owner(s): Indicate Individual, Partners, Etc. (If Corporation, Show Title of Officers). Attach Additional Sheet If Necessary.

Name	Title	Address
Somnath Chattopadhyay	Vice President, Global Supply Chain	One Amgen Center Drive, Thousand Oaks, CA 91320
Simon Hotchin	VP Regulatory Affairs	One Amgen Center Drive, Thousand Oaks, CA 91320

Which of the following entities do you sell / ship to?

- [x] Retail Pharmacies
- [x] Hospital Pharmacies
- [ ] Physicians
- [ ] Dentists
- [ ] Veterinarians
- [x] Other Wholesalers
- [x] Other Clinics and Distribution Partners

Categories of product being sold / shipped into New Hampshire at wholesale?

- [ ] Controlled Substances
- [x] Human Prescription Drugs
- [ ] Veterinary Prescription Drugs
- [ ] Prescription Devices (At Wholesale)
- [ ] Medical Gases (At Wholesale)
- [x] Other Combination Products

Attachments & Declaration / Signature By Company Representative:

I affirm that I am the person authorized to sign this application for licensure and affirm that this application (including any accompanying documents) has been examined by me and to the best of my knowledge and belief is a true, correct and complete application, and if the registration herein applied for is granted, I hereby agree to and do submit to the jurisdiction of the New Hampshire Board of Pharmacy and to the laws and rules of this State.

ATTACHMENTS REQUIRED:

(ALL REQUIRED ATTACHMENTS MUST BE SUBMITTED OR YOUR APPLICATION WILL NOT BE PROCESSED)

I confirm that the following attachments have been attached to this renewal form:

- [x] 1. A copy of the facility's current license/registration issued by the Board of Pharmacy or other state regulatory agency where the facility is located (home state); See attached.
- N/A 2. A copy of the facility's current Federal DEA Registration Certificate if shipping controlled drugs; Not applicable. Amgen does not store, manufacture or distribute controlled drugs.
- [ ] 3. A copy of the facility's most recent inspection report issued by either the FDA, NABP / VAWD Accreditation, or State Board of Pharmacy where the pharmacy is located (home state). Please see attached memo regarding inspection.
- [ ] 4. Attach 2 photographs of the existing exterior of the facility in which the applicant is located. These photographs shall include any outside signage. Artist sketches or architect plans or drawings are not acceptable. Facility under construction.
- [ ] 5. Attach at least 4 photographs of the interior of the facility showing legend drug storage areas, refrigeration units and any specially constructed areas for storage of controlled substances. Facility under construction.
- N/A 6. In-state applicants must also submit a scaled floor plan of the facility. Not Applicable. This application is for an out of state manufacturing facility in Ohio.
- [x] 7. Attach a list of all states (spreadsheet format preferred) where currently licensed, and include license number. See attached.
- [x] 8. Check for $500 payable to "Treasurer, State of New Hampshire".

Signature: _____ Title: VP Global Supply Chain Date: 8.31.2022

Somnath Chattopadhyay

INCOMPLETE APPLICATIONS OR APPLICATIONS WITHOUT REQUIRED ATTACHMENTS CANNOT BE ACCEPTED.

DO NOT LEAVE ANY BLANK SPACES – IF NOT APPLICABLE, WRITE N/A & THE REASON IT DOES NOT APPLY.

ANY SUBSEQUENT CHANGES TO THE INFORMATION ON THIS FORM MUST BE REPORTED TO THE BOARD IN WRITING WITHIN 30 DAYS OF CHANGE.

EXPECTED PHOTOGRAPH AND FDA INSPECTION TIMING

APPLICATION CONTENT (Ph 1001.03)

Currently this facility is under construction, photographs are not included. This requirement will be fulfilled once the interior and exterior photographs become available (approx. Q2 2023).

The FDA FEI is 3020740318 and the DUNS number is 118378297. We plan to register in the FDA DECRS database and expect FDA inspection closer to the time of expected distribution, Ql 2024.

Distribution is expected to begin approximately Q1 2024 and will be performed by our Amgen USA, Inc. facility in Louisville, KY which holds an active distribution license in your state # 3820.

RECEIVED
SEP 22 2022
OPLC-FINANCE

Amount $500 –

Check #648927

AMGEN

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805-447-1000

September 8, 2022

State of New Hampshire
7 Eagle Square, Suite 300
Concord, NH 03301

Dear Ladies and Gentlemen:

This memorandum provides information regarding a new Amgen Inc. Drug Manufacturing facility to be located at:

4150 Ganton Parkway
New Albany, OH 43054

We are submitting the required non-resident drug manufacturer application to obtain a license in your state.

Currently, this facility is under construction. Per NH Regulations Chapter Ph1000, Ph1001.03 Application Content: "Provide photos of the facility". We are unable to provide current photos of the facility immediately. We will fulfill this requirement as soon as photos become available.

The FDA FEI is 3020740318 and the DUNS number is 118378297. We plan to register in the FDA DECRS database and anticipate FDA inspection closer to the time of expected distribution.

Distribution is expected to begin in approximately Q1 2024 and will be performed by our Amgen USA, Inc. facility in Louisville, KY which holds an active distribution license in your state, **#3820.**

Thank you in advance for your assistance with processing this application.

Please contact me via email at: statelicensing@amgen.com with any questions.

Sincerely,

Susan Simons
US State Licensing
Senior Manager, Global Regulatory Affairs
statelicensing@amgen.com

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2023.

AMGEN INC.

4150 Ganton Pkwy

New Albany, OH 43054-3522

License Number: 0150000068

Manufacturer - Category 2

Expiration Date: June 30, 2023

CLASS: Manufacturer - Category 2
BUSINESS TYPE: MF – Manufacturer

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
SANDRA RODRIGUEZ-TOLEDO	Sandra Rodriguez-Toledo

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Amgen Inc. (Ohio) - State License List					
State	Business	License Type	License #	License Status	Exp.
Ohio	Amgen Inc.	Manufacturer - Category 2	0150000068	Active	6/30/2023
West Virginia	Amgen Inc.	Drug Manufacturer	MR0552391	Active	6/30/2024

THIS DOCUMENT IS PRINTED ON WHITE SAFETY PAPER FEATURING FLUORESCENT FIBERS AND A TRUE WATERMARK - HOLD TOWARD LIGHT TO VIEW

IMS Health & Quintiles are now

QVIA

Shared Business Services
1510 Valley Center Parkway, Suite 130
Bethlehem, PA 18017

Amgen Inc

THE NORTHERN TRUST COMPANY
Chicago, IL 0710
Payable Through
Northern Trust Bank/ DuPage
Oakbrook Terrace, IL

DATE
08/24/22

648927
70-2382
719

NET AMOUNT
$500.00

PAY FIVE HUNDRED and DOLLARS DOLLARS

TO THE ORDER OF

SP 1 *

TREASURER STATE OF NEW HAMPSHI
121 SOUTH FRUIT STREET
CONCORD NH 03301

Cash Promptly, Not Valid After 120 Days

⑈0006489 27⑈ ⑆071923828⑆ 03048709 2⑈

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New Albany, OH 43054

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Thank you in advance for your assistance with processing this application.

Please contact me via email at: statelicensing@amgen.com with any questions.

Sincerely,

Susan Simons
US State Licensing
Senior Manager, Global Regulatory Affairs
statelicensing@amgen.com