

Drug and Medical Device Registration FAQ

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New Jersey Department of Health | Public Health & Food Protection Program
Wholesale Drug or Medical Device Business Registration

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Types of Submissions

When is it appropriate to submit a new application form F-2?

Utilize the *Registration of Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business* application form F-2 only to apply for a new registration for a new legal entity. All submissions of form F-2, upon approval, will result in a new registration number.

Do I need to submit a new application for a new or changed location?

Multiple locations that are operated by the same business entity may be registered under the same registration number. There is no need to submit a new application for each location.

How do I add, change or remove a location on my existing registration?

Multiple locations may be associated with one registration. You may CHANGE, ADD or REMOVE a location on your registration at any time by submitting the following:

- Signed letter explanation of the changes to be made. Include:
 - Registration number (beginning with “500”)
 - Name and contact information of the Designated Representative for each new location.
 - Short description of operations at each new location.
 - The effective date of the change.
 - If a manufacturing or warehouse facility is closing, include verification that all remaining drug, medical device or API inventory has been accounted for, reclaimed and/or disposed of properly.
- For each new out-of-state location, attach a copy of the resident state wholesale license.
- **\$20 Processing Fee** per letter (if submitted separately from the annual renewal).
 - The fee is only applicable to new locations. There is no fee to remove a location.
 - If a change or addition of location is submitted accompanying the annual renewal fee, the \$20 processing fee is **waived**.

Only your first-party locations need to be listed on your registration. Please do not include contract manufacturers, third-party logistics providers, chain pharmacy distribution centers or any other third-party locations.

How do I change the business name on my registration?

You may CHANGE your business name at any time of the year by submitting a signed letter request. Attach a copy of the resident state license showing the new business name, if applicable, or legal documentation to support the name change. There is no fee to change the name on your registration.

How and when should I notify the Department of company changes?

Within 30 days following a change of corporate structure, change of parent or grandparent company, change of officers, or change of designated representative that will not result in a direct modification of the New Jersey wholesale registration, notification may be submitted via email with your “500-” series registration number and “NOTICE OF CHANGES” in the subject line to: wholesaledrugs@doh.nj.gov

How do I discontinue my registration?

If you are ceasing wholesale activities and wish to DISCONTINUE your registration please submit a signed letter on company letterhead indicating the registration number to be discontinued, the reason for discontinuance, and the effective date. If a manufacturing or warehouse facility is closing, include verification that all remaining drug, medical device or API inventory has been accounted for, reclaimed and/or disposed of properly. Attach the most recent original NJ wholesale license, if available.

New Applications

Does my business need to be registered with the Department?

This office is unable to offer legal advice to businesses and cannot evaluate for licensure without submission of application. Requirements for registration are based on the definitions and exemptions provided in NJAC 8:21-3A.3, NJSA 24:1-1 and NJSA 24:6B-14. The regulations are linked on the Drug and Medical Device Registration webpage:

<http://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/>

Is this the correct registration for a Durable Medical Equipment provider?

The *Drug and Medical Device Registration* is not applicable to direct-to-patient equipment providers.

How long is the review process for a new application?

The review process for a new wholesale registration application is 30 days. If the application is found to be deficient, a letter will be mailed to the mailing address specified on the application form. NJ resident distribution locations and offices will be subject to inspection before approval.

Which locations should I list on pages 1-2 of the new registration application?

All establishment locations that are directly operated by the applicant business, that conduct wholesale business into or within New Jersey, and are submitted for consideration by the Department for registration under the applicant business must appear within number 17 pages 1-2 of the initial registration application. Only your first-party locations need to be listed on your registration. Please do not include contract manufacturers, third-party logistics providers, chain pharmacy distribution centers or any other third-party locations.

What information must be submitted for each location submitted for registration?

When submitting for a new registration, locations to be registered must be listed within number 17 pages 1-2 of the application form. Under "Activity Completed" check all applicable boxes. Only check "Manufacturer" if product is physically manufactured at the location and the location is registered as a manufacturing facility with FDA. Virtual Manufacturer office locations should check "Other" and write "Virtual Manufacturer" on the line provided. Applicants are welcome and encouraged to attach a second page to provide details of operations. Please provide the name and contact phone number of the person present and in charge of the applicant's operations at that location. For each applicant location outside New Jersey, submit the resident state wholesale license or registration which shows the applicant's name and location address.

[May I submit a residential home office for registration?](#)

Per NJSA 24:6B-20 all establishments which conduct wholesale distribution activities, including all office operations, must be a commercial location. Applications which list a residential location for registration will be ineligible for approval.

[May I operate a wholesale business from a pharmacy?](#)

Per NJAC 8:21-3A.5 a retail pharmacy or dispensing location wishing to conduct wholesale business shall operate the wholesale business under a separate name and at a separate location other than that of the pharmacy or dispensing location.

[Do I need a New Jersey Registered Agent?](#)

All non-resident applicants are required to submit the name, contact information and New Jersey office address of an appointed New Jersey Registered Agent. The Department cannot recommend a Registered Agent.

[Do I need to submit a full product list?](#)

A full product list is required to be submitted. Longer lists may be attached as a CD or flash drive. If the required product information is available on the business website, a web address is also acceptable. If a new business does not yet have a list of products, or if the list fluctuates frequently, please provide detailed information regarding the type and source of products to be distributed.

[Do I need to submit the full Articles of Formation for my business?](#)

It is not necessary to submit the full Articles of Formation. A valid Certificate of Incorporation or Certificate of Formation is sufficient to satisfy the attachment requirement for an established business.

[What is a Federal ID Tax Certificate and where can I find it?](#)

Please submit a document or letter provided by the IRS which verifies the company's Tax ID number. If this is not available, a W-9 form is also acceptable.

[Do I need a Controlled Dangerous Substance license?](#)

Please contact the New Jersey Office of Drug Control at 973-504-6351.

[Does a CPA need to sign my form?](#)

The *Certified Public Accountant Signature* section of the initial application form is only required if the company is submitting a fee of only \$50. A CPA must sign only to verify that the company qualifies for the discounted application fee. If a company submits \$200 or more, a CPA signature is not required.

[How do I request an expedited review process of my application?](#)

This office does not offer expedited processing and cannot under any circumstance guarantee a processing time less than 30 days. An applicant is welcome to submit a cover letter to describe emergency time constraints, which may be considered during the review process. Applications will not be expedited based on phone calls or e-mail correspondence.

[Can a business operate in New Jersey while its application is under review?](#)

An applicant may not conduct wholesale drug or medical device business in the State until a registration is issued in the applicant's name.

What is the status of my new application?

New application forms must be submitted via courier or certified mail to enable tracking capability. Please use the date of delivery as verification that your application has been received by this office. Please allow 30 days for processing and review. If the review finds the application deficient, a letter will be mailed to the mailing address on the application, to the attention of the signing officer. If an applicant location qualifies for inspection, at the conclusion of the review a State inspector will directly contact the Responsible Person of the location to schedule an inspection. Upon issuance, the new registration information will immediately become available on the Drug and Medical Device registration verification webpage: <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdSearch.aspx>

My resident state license has not yet been issued. May I submit the NJ application?

A non-resident application will not be approved for registration until a license has been issued by the resident state, or a statement by the resident state Board of Pharmacy has been provided that excludes the applicant from licensure in the resident state.

Inspections

Will my New Jersey location receive an inspection?

All new in-state locations which conduct wholesale distribution activities, including office operations, will receive an inspection by the Department.

Why am I required to have an inspection?

The State of New Jersey conducts the inspections of all wholesale distributors of drugs and medical devices that are currently registered or have applied for the registration in NJ on a three-year schedule.

Will an inspector call me to schedule an inspection?

Upon completion of review of the initial application or request to add a new location, the listed Responsible Person or Designated Representative of the location will receive a call from an inspector to schedule the initial inspection. Routine inspections of currently registered facilities may be unannounced.

What should I know about the inspection?

The inspections are done to determine compliance with the Registration of the Wholesale Distributors of Drugs rule, NJAC 8:21-3A, which can be accessed through the Drug and Medical Device Registration webpage: <http://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/>

What happens if an inspection results in a Conditional Satisfactory evaluation?

After the inspection is conducted the facility is provided with an inspection report. Facilities rated Conditional Satisfactory will be reinspected on or after 30 days from the date of the initial inspection. 60% or more of the violations are expected to be corrected in order to receive a satisfactory rating on the reinspection.

When will I receive the new license for my New Jersey location?

Upon completion of the inspection, the facility will be provided with the inspection report. If the facility receives a Satisfactory rating the report will undergo review by the office for issuance of a Drug and Medical Device registration. A Conditional Satisfactory rating will result in a reinspection. The registration will only be issued to the facilities that have received a satisfactory inspection rating and have concluded final review.

Do I need an inspection in order to apply for a license in other states?

Follow the requirements of the State where you apply for the registration. If your firm is registered in NJ the NJ inspection report may be required to obtain an out-of-state registration.

How may I request a new inspection of a currently registered location?

A facility may request an inspection by mail or via email to wholesaledrugs@doh.nj.gov with your “500-” series registration number and “REQUEST FOR INSPECTION” in the subject line. Please provide the name and contact phone number of the Person In Charge at the location, and a brief description of operations at the location to be inspected.

Drug and Medical Device Registrations

When does my registration expire?

All *Drug and Medical Device Registrations* expire on January 31st of each year.

How do I verify the status of my current registration?

The status of a NJ Drug and Medical Device registration is available online at:
<http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdSearch.aspx>

How do I submit a license verification form for completion by the Department?

The Department can no longer complete license verification forms for applications for other states. Verification certificates are only available from the online verification webpage, linked below. Print the certificate and attach a copy of the current New Jersey registration to fulfill verification requirements in other states. The verification page may be found at:
<http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdSearch.aspx>

How may I request a copy of my registration?

Please send an email request to wholesaledrugs@doh.nj.gov with your “500-” series registration number and “REQUEST FOR COPY OF REGISTRATION” in the subject line. Please specify whether an email or printed registration copy is requested. Registration copies are available to representatives of the registered business.

Registration Renewal

When should I expect to receive my renewal form?

Renewal forms are mailed in mid-November. The renewal form F-13 is also available on the Department website: <http://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/>

May I submit my renewal early?

Renewal applications will begin to be accepted in November.

The Submission Process

What methods of payment are available?

Payments may be made via check/money order or online payment. Online payment with a credit card or e-check is available at our website: <http://nj.gov/health/ceohs/food-drug-safety/epayments.shtml>

Who should I make a check payable to?

Checks and money orders should be made payable to *NJ Department of Health*.

Can I submit a check and application separately?

Checks and applications which are received separately will not be processed and will be returned to the applicant.

Is my registration automatically renewed when I submit an online payment?

Renewal payments submitted via the online payment system are not sufficient to renew a registration. The online payment system is a payment processing service only and is in no way an application for renewal. The signed and completed form is required to be mailed in hard copy in order for the license to be renewed.

Where should I send my application?

Paper applications, attachments and payment may be mailed to the following address:

NJ Department of Health
Public Health & Food Protection
PO Box 369
135 East State Street
Trenton, NJ 08625

May I drop off my application in person?

Walk-ins are not accepted and there is no receptacle for personally delivered applications. All applications must be mailed via USPS or courier to ensure proper processing.

Who should I contact if I have additional questions?

Please call the Public Health & Food Protection program at 609-826-4935 or email wholesaledrugs@doh.nj.gov with any questions.