# SUBMITTING A WAIVER, EXCEPTION OR EXEMPTION TO FDA

HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

# SUBMITTING A WAIVER, EXCEPTION OR EXEMPTION TO FDA

August 2024

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About the Healthcare Distribution Alliance:

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

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*This guide provides voluntary, suggested processes regarding submitting a Waiver, Exemption or Exception request. This document is based on evolving understanding of DSCSA requirements and does not constitute and is not intended to represent legal advice. Each company must make its own business decision and should consult with its legal counsel, regulatory compliance specialists and trading partners for further implementation guidance.*

# WHAT IS A WAIVER, EXEMPTION OR EXCEPTION (WEE)?

Section 582 of the Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 360eee-1, sets out the requirements applicable to trading partners for the implementation of the Drug Supply Chain Security Act (DSCSA). Section 582 requirements include affixing product identifiers on drug packages and cases (and only transacting products with identifiers), exchanging and maintaining product tracing data, and conducting verification. FDA has the authority to grant waivers, exceptions, and exemptions (WEEs) from § 582 requirements. An authorized trading partner and other stakeholders may request that FDA grant a WEE excusing compliance with some or all of these requirements.

FDA currently maintains a webpage that details how to submit a WEE request, which is available here. Stakeholders should reference this webpage as they consider submitting a request.

## WHO MAY REQUEST A WEE?

### Exceptions:

**A manufacturer or repackager may request an exception to the requirements relating to product identifiers** if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the required information.

### Waivers:

**An authorized trading partner may request a waiver if the above requirements would result in an undue economic hardship** or for emergency medical reasons, including a public health emergency declaration.

### Exemptions:

**An authorized trading partner or other stakeholder may request an exemption** for other products or transactions.

**An exception is limited to relieving the manufacturer or repackager from the duty to affix product identifiers to drug packages. In contrast, trading partners — manufacturers, repackagers, wholesale distributors and dispensers — may seek a waiver or exemption. Stakeholders who are not trading partners may only seek an exemption.**

# WHEN DO I NEED A WAIVER OR EXEMPTION?

Waivers and exemptions requests are available when a trading partner does not believe it can comply with requirements in § 582. Stakeholders who are not trading partners may also submit an exemption request.

At this stage, most requesters may be looking for relief from the package-level requirements in § 582(g)(1) that were effective November 27, 2023. They include:

(A) Transaction Information (TI) and Transaction Statement (TS) must be exchanged in a secure, interoperable and electronic manner.

(B) TI must include the product identifier at the package-level for each package included in the transaction (referred to as "serialized data" or "serialized product tracing data").

(C) Systems and processes for verification of products at the package-level.

(D) Systems and processes necessary to promptly respond with TI in response to an appropriate tracing request by a government official.

(E) Systems and processes necessary to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer in response to appropriate tracing requests.

(F) For saleable returns, systems and processes to associate the saleable return product with the TI and TS associated with that product.

However, FDA granted a one-year stabilization period to allow systems to mature as trading partners worked to fully comply with these § 582(g)(1) requirements. FDA has stated it will not extend the stabilization period beyond November 27, 2024. After November 27, a trading partner must receive accurate, complete and timely serialized product tracing data from the seller to purchase a covered drug and must provide that serialized data to its customer in each transaction. Other requirements of § 582(g)(1), including tracing and verification at the package-level, assume trading partners are exchanging and maintaining serialized product tracing data. If a trading partner does not believe it will be able to comply with § 582(g)(1) by November 27, 2024, it should consider submitting a request for a waiver or exemption.

# WHERE DO I SUBMIT A WAIVER OR EXEMPTION?

## GENERAL SUBMISSION REQUIREMENTS

- Product-specific requests for drugs regulated by the Center for Drug Evaluation and Research (CDER) should be submitted through the CDER NextGen portal.
- Product-specific requests for drugs regulated by the Center for Biologics Evaluation and Research (CBER) should be submitted as follows:
  - Requests associated with products under approved applications should be submitted in eCTD format through FDA's Electronic Submissions Gateway as product correspondence to the application. This requirement is applicable only to the product application holder; other stakeholders and trading partners would not be able to submit controlled correspondence to the approved license application.
  - Requests exclusively for CBER-regulated products but not associated with an application should be emailed to DSCSA-CBER-WEER@fda.hhs.gov.
- Requests that are not related to specific products or where the lead center is uncertain or unknown should be submitted through FDA's CDER NextGen portal.

## WHOLESALE DISTRIBUTOR SUBMISSIONS

### Product-Specific Requests

If you are making a product-specific request by NDC, you should determine whether the product is regulated by CDER or CBER. CDER-regulated product submissions are made to the NextGen portal and CBER-regulated product submissions would be made to DSCSA-CBER-WEER@fda.hhs.gov. In most, but not all cases, you can make this determination based on the product's application.

- Products approved under New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) are usually regulated by CDER.
- Products licensed under a Biologics License Application (BLA), including biosimilars, are usually regulated by CBER.

The type of application or license is available from several sources:

- The manufacturer's new product form
- FDA's Drugs@FDA: FDA-Approved Drugs
- FDA's NDC Directory Lookup
- FDA's Purple Book Database of Licensed Biological Products
- FDA's Orange Book Database for Approved Drug Products

The application number and/or listing should include "NDA," "N," "ANDA" or "A" for drugs and "BLA" for biologics.

For historical reasons, CBER regulates some products with NDAs and ANDAs, while CDER regulates products with BLAs. Some prescription drugs are also marketed without an approved application. The FDA instructs that where it appears uncertain, the request should be made to the CDER NextGen portal.

### Non-Product-Specific Requests

If you are seeking a waiver or exemption that is not productspecific (such as one covering your entire organization or all transactions by your organization), the FDA states that you should submit the request through the CDER NextGen portal. FDA states that a request that is "exclusively" for CBER-regulated products that is not associated with a license application should be emailed to DSCSA-CBER-WEER@fda.hhs.gov. This would appear to apply only if you are seeking a waiver or exemption for your organization and you handle only biologics regulated by CBER. FDA states that all other requests that are not product-specific should be submitted through the CDER NextGen portal.

## WHEN SHOULD I SUBMIT A WAIVER OR EXEMPTION REQUEST?

You can submit a request for a waiver or exemption at any time. However, if you are seeking relief from § 582(g)(1) requirements after the stabilization period ends on November 27, 2024, FDA recommended submitting the request by August 1, 2024.

## HOW LONG WILL IT TAKE FDA TO DECIDE MY REQUEST AND WHAT HAPPENS WHILE MY REQUEST IS PENDING?

It is the experience of some stakeholders that FDA takes several months to respond to WEE requests. For requests for relief from § 582(g)(1) requirements after the stabilization period, FDA has stated that if requests are submitted by August 1, 2024, it will try to respond before the November 27, 2024, deadline. However, the agency also states that it may not be able to do so.

FDA has stated that a trading partner's obligation to comply with § 582(g)(1) **will not be paused or extended** while its waiver or exemption request is pending. The FDA has also said that the agency expects all trading partners to continue efforts to meet applicable requirements until FDA has acted on the request.

**You should not assume that FDA will grant your request or that it will do so in the time frame that you may need.**

# WHAT SHOULD I INCLUDE IN MY REQUEST?

It is generally understood that most requests may be submitted to the CDER NextGen portal. Regardless of whether you use the NextGen portal, **you should consider also submitting a separate letter that sets out the basis for your request.**

## NAVIGATING THE NEXTGEN PORTAL

### Creating an Account

You should create an account to submit requests to the NextGen portal. Information requested includes your organization's name, contact information and DUNS number. If you do not have a DUNS number, it appears that you can enter "999999999."

### Entering Information about Your Request

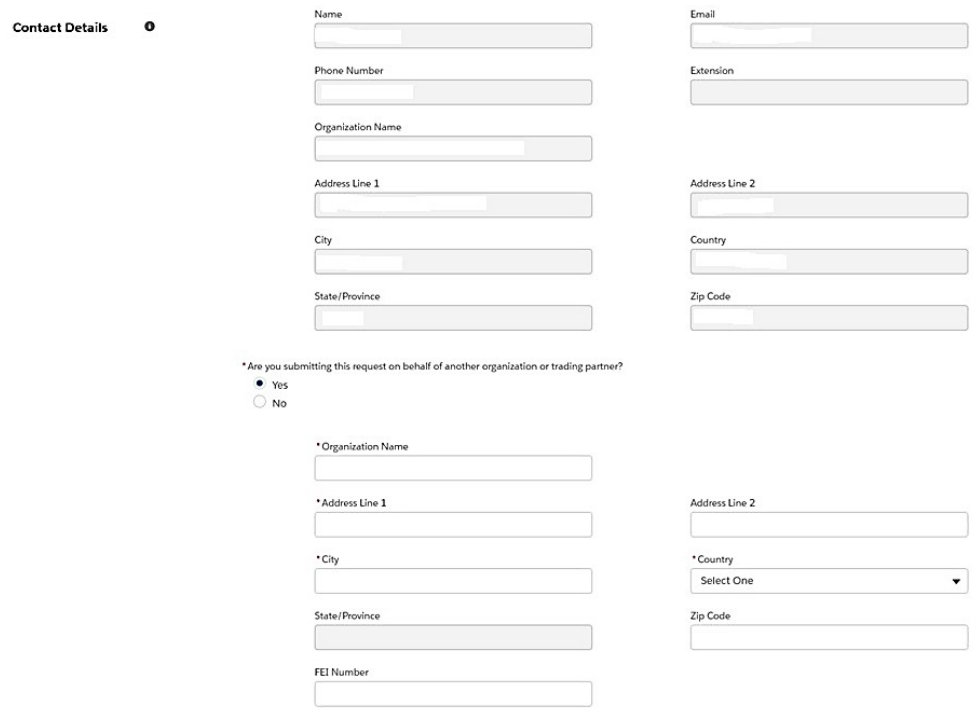
The NextGen portal is a gateway for the submission of numerous different documents to CDER, including the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) reporting, controlled correspondence to a drug application, and orphan drug submissions. The portal also has three DSCSA-related functions: 3911 reporting, responses to tracing and verification requests initiated by FDA, and requests for WEEs. To submit a WEE, click on DSCSA Waiver, Exception, and Exemption Request.

You should always read any announcements on the NextGen Portal Welcome page. They will appear on the right hand side of the page. FDA also frequently modifies and improves the WEE submission interface. This guide reflects the WEE request process in the NextGen Portal as of September 13, 2024. When you submit your WEE request, you may find the NextGen Portal is slightly different than this guide.

Your submission should be as complete and as clear as possible. However, you may also explain the basis for your request fully in a separate letter. You may also attach additional documentation to support your request. If FDA needs additional information or clarification, they are likely to contact you.

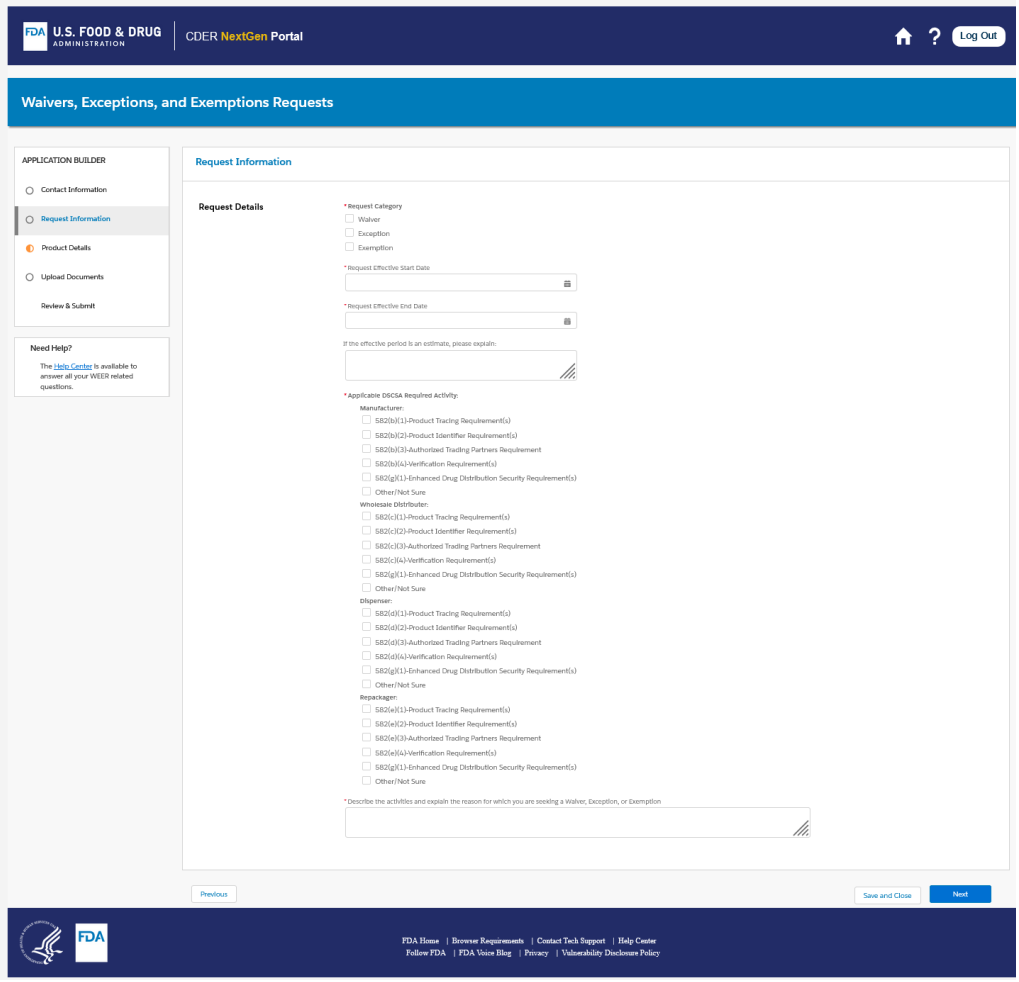
#### Contact Information

The following is a screen capture of the Contact Information page. Note that you have the option of submitting on behalf of yourself, another organization or a trading partner. While the form indicates a Federal Establishment Identifier is necessary, it is generally understood that it is not critical. The DSCSA permits trading partners to submit waiver and exemption requests; and other stakeholders may also submit exemption requests.




## Request Details

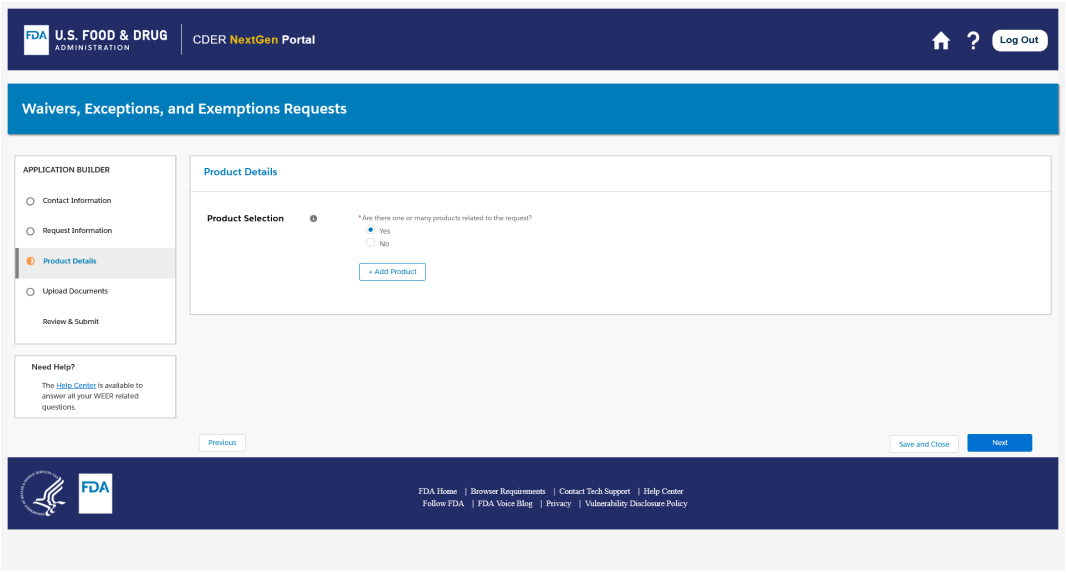
The following is a screen capture of the next part of the submission, "Request Details." An explanation of the boxes you must check and complete follows.



- Identify whether you are requesting a waiver (for economic hardship), an exception (from affixing a product identifier) or an exemption (for other products or transactions).
- Identify a proposed start and end date, and an explanation if your end date is an estimate.
- Check the boxes for the sections of the DSCSA for which you are seeking the waiver or exemption.
    - The options in the menu relate back to the general DSCSA requirements applicable to each trading partner in § 582: § 582(b) (for manufacturers), § 582(c) (for wholesale distributors), § 582(d) (for dispensers) and § 582(e) (for repackagers).
    - Sections 582(b),(c),(d) and (e) all follow a similar organization structure that is reflected in the dropdown menu. For wholesale distributors, § 582(c)(1) sets out requirements for the receipt and provision of TI, TS and the now defunct TH as well as association requirements for saleable returns; (c)(2) requires transactions only of product with identifiers; (c)(3) requires engaging in transactions only with trading partners who are authorized; and (c)(4) describes verification systems and processes, including verification of saleable returns prior to resale.
    - FDA recently updated the portal to provide an option to select "582(g)(1)-Enhanced Drug Distribution Security Requirement(s)". These are the 2023, package-level, serialized data requirements. Most requests at this time are seeking relief from 582(g)(1) enhanced requirements. If you are only seeking relief from some, but not all 582(g)(1) requirements, you should include this information in your letter. You could also include some of this information in the text box, such as, "We are seeking relief only from the requirements of sections 582(g)(1)(A),(B),(D), and (E). We do not seek relief from the requirements of sections 582(g)(1)(C) and (F).
    - If you are submitting a request to cover a variety of different products, you may indicate in the same text box that the request is 'for all products' or 'multiple different products.'
    - You should provide more details about your request for a waiver or exemption from § 582(g)(1) requirements in your accompanying letter.
    - Review § 582(c) and (g) with your legal counsel and/or regulatory affairs team when completing this section to identify, as best you are able, the legal obligations you are seeking relief from.
- In the final box, you should summarize your request and then cross-reference the letter you attach to your submission. The box has a limit of approximately 3,900 characters.

## Product Details

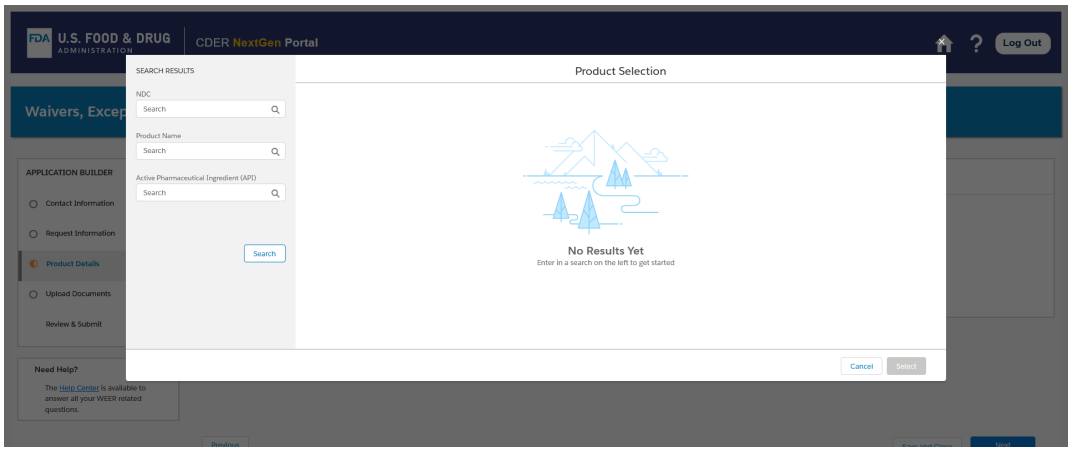
If you are making a request regarding a specific NDC or multiple NDCs, this information may be entered in the "Product Details."



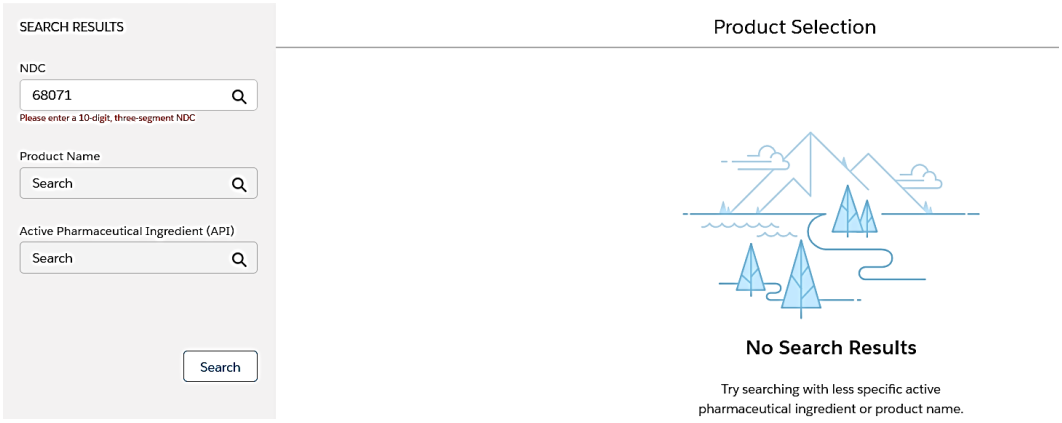

You should click "No" if your request is not limited to specific products. If you click "Yes," the "+Add Product" button will appear. If you click on +Add Product, a window will appear (shown below) that allows you to search for the relevant product(s) by the product's 10-digit NDC, name (either brand or generic name) or active pharmaceutical ingredient.

The NextGen Portal does not require that you manually enter each product for which you seek an exemption. You may select "Yes" in the "Product Details" box and then click "Next" at the bottom of the page. The next page allows you to upload supporting documentation listing the product inventory subject to the request. The Portal accepts documents in the following formats: pdf, doc, docx, xls, xlsx, ppt and pptx. You should identify the products in this submission by NDC, and ideally should include brand name (if applicable), generic name, active pharmaceutical ingredient, application number, strength and dosage form.

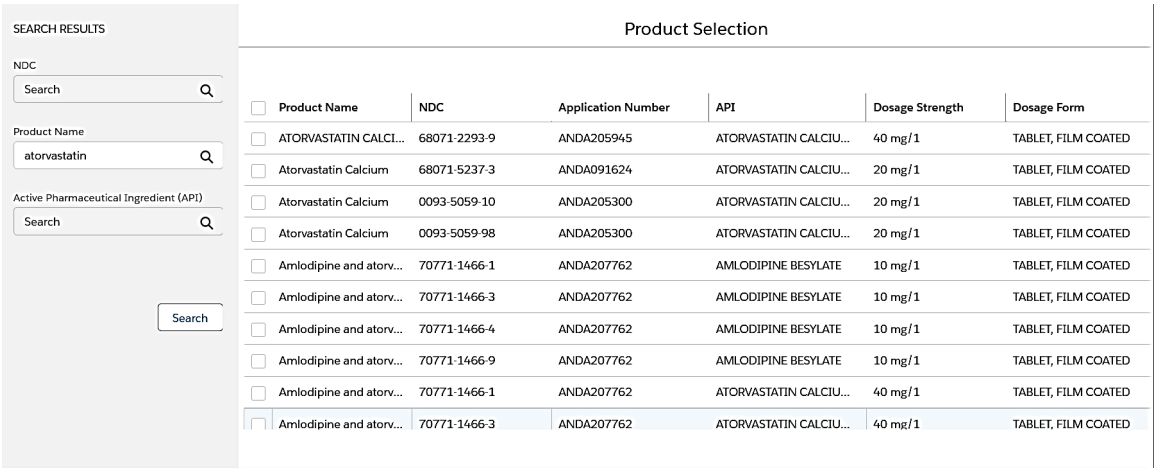
If you click "Yes" and the +Add Product button to manually enter product information, the following will appear:



You cannot search solely by a company's labeler code; you must enter the 10-digit full NDC number.




If you enter a brand or generic name, such as "atorvastatin," every product in FDA's database that includes that name by NDC appears. The dropdown menu does not identify the drug's manufacturer, only its NDC (including labeler code).




## Upload Documents

The final menu gives you the option to upload documents. This is where you should consider including a letter giving more information about the basis of your request. The content of this letter is discussed further below. You should also upload any other supporting material including, if relevant, and if you opt to do so, a document that identifies the products for which you are seeking an exemption or waiver.

## Other Submission Details

Once you upload your documents, you continue to the certification page and then submit your request. You can save your request as a draft and return to it later and make changes to it. The portal appears to save requests automatically, and you can find them again if you log in and return to the DSCSA Waiver, Exception, and Exemption Request page.

## YOUR LETTER

The letter accompanying your request should include additional information that may be persuasive to FDA.

The WEE Final Guidance and the webpage, Requesting a waiver or exemption after the stabilization period, describe certain information you should consider including in your request to aid FDA in its consideration. The guidance predates the NextGen portal so some of the information appears to be duplicative and would already be entered into the portal. However, repeating all requested information in a single document could be useful for the agency's review.

- **Name, telephone number and email address** of an individual whom FDA can contact about matters relating to the WEE.
- **Name and address of the trading partner(s)** that the proposed WEE exemption would cover.
- **Description of the activities and/or products** (including the product name and NDC number) for which the proposed WEE is being sought.
- **Identification of the specific statutory provision(s) of section 582** to which the proposed WEE would apply. If you are requesting a waiver or exemption from § 582(g)(1) package-level 2023 requirements, you should explain this in your letter.
- **Description of the measures or controls that will be implemented to ensure the safety and security of the drug supply chain while operating under a WEE.** This discussion may be particularly important for FDA at this late stage of DSCSA implementation.
    - You should consider what you can do to help ensure that the supply chain remains at least as secure as it is now, even if FDA grants your waiver or exemption.
    - You should explain what current levels of DSCSA supply chain security you will be able to maintain and what 2023 requirements, if any, you are able to implement and comply with.
    - For instance, if the request is to obtain an exemption or waiver for an NDC, you could describe the processes you have or would put in place to minimize the risk of illegitimate products entering your warehouse. If you are asking for the ability to resell a product without having been provided serialized data, you should describe the security measures you have in place, the diligence you perform on suppliers, what suppliers would have to provide you, and what inspections your products undergo during receiving and pick, pack and ship. The measures you can operationalize to maintain supply chain security will be highly dependent upon the facts of the waiver or exemption and your organization's business needs.
- **Requested effective period.** FDA recognizes in the WEE Final Guidance that a product subject to a WEE can persist in the supply chain until expiration, and long after the WEE itself has expired. Your letter should include, if applicable, any suggestions for the smooth transition of a granted waiver and exemption, and how product that was introduced into the supply chain under a WEE should continue to be handled.
- **Any unique or special circumstances of a product and/or transaction.**
- **Detailed statement describing the reason(s)** justifying the proposed WEE, as well as pertinent supporting documentation, as applicable, to support the request. This information is also highly fact-specific.
- **Impacts on other trading partners.** In the WEE Final Guidance, FDA recognizes that a WEE may affect DSCSA compliance for downstream trading partners. You should describe, to the extent you are able, how your requested waiver or exemption will lessen, (or at least not increase), the burdens upon your downstream customers.

- **Notification of other trading partners.** The WEE Final Guidance recommends that a trading partner who obtains a WEE should notify its trading partners. Your letter should address, to the extent downstream trading partners are affected, your plan for notification.

In addition, for a waiver or exemption from § 582(g)(1) 2023 package-level tracing requirements, FDA recommends providing information to demonstrate you have been working diligently to implement the law. The agency recommends including the following in your request:

- **Steps that have been completed** to implement the section 582 requirements for which the waiver or exemption is being sought.
- **Explanation detailing why additional time is needed.**
- **Steps that will be taken to fully implement requirements**–what your plan is to come into full compliance and when.
- **Number of full-time employees.**
- **Identity of the manufacturer** who holds the approved application(s) for the product(s) involved if a co-licensed partner or affiliate submits a waiver or exemption request. If your request is to seek an exemption from § 582(g)(1) requirements for a particular manufacturer and some or all of its NDCs, your request should identify the manufacturer.

## ADDITIONAL POINTERS

FDA may receive many requests for waivers and exemptions. Your submission should make it as easy as possible for FDA to approve your request.

- Though the letter may require technical and operational discussions, simplifying your request as much as possible is recommended.
- You should be sure to include all the elements that FDA identifies in the WEE Final Guidance and the following webpage. As the agency may check your submission against a checklist to ensure it is complete, your request should be organized and labeled as FDA sets out. If a piece of information requested is not relevant to your submission, such as particular NDCs or the identity of a manufacturer, state: "Not Applicable."
- A thoughtful submission should, to the extent possible, address the agency's concerns for continued patient access to needed medicines ***and*** maintenance of current levels of supply chain security.
- If you are requesting relief from § 582(g)(1) 2023 package-level requirements, it is recommended that you explain what you have done so far to comply.
    - This does not have to be exhaustive. You should demonstrate your diligence and your good faith efforts and explain how you intend to use the time FDA gives you, should it grant the request.
    - To the extent possible, make your request narrow — limit it to time, specific trading partners and/or NDCs.

# RESOURCES

## Final Guidance

- Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (August 2023) (WEE Final Guidance)

## FDA Webpages

- The Drug Supply Chain Security Act (DSCSA) Waivers, Exceptions, and Exemptions (updated June 12, 2024)
- DSCSA Portal in CDER NextGen
- Waivers and Exemptions Beyond the Stabilization Period

## Other Resources

- DSCSA Portal Reference Guide for information about registering and creating an account in the portal.
- Statute, § 582(a)(3), Federal Food, Drug and Cosmetic Act (FDC Act), 21 U.S.C. § 360eee-1(a)(3), as amended by the Drug Supply Chain Security Act (DSCSA). (Section 582(a)(3) is excerpted here.)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