Listing Updates and Delisting

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Overview

- Who must update drug listings and when?
- What information must be submitted when updating drug listing information?
- Who must delist a product and when?
- How to delist and update drug listing information using CDER Direct?
- Challenge Question

Learning Objectives

- Describe the drug listing requirements
- Identify who needs to update drug listing and when
- Identify who needs to delist and when

Who must update drug listings and when?

- Under 21 CFR 207.57(b), each registrant must review and update their drug listing information no later than June and December of each year.

- Under 21 CFR 207.57(c), registrants are encouraged to update listing information at the time of any change affecting information previously submitted.

What information must be submitted when updating drug listing information?

- Under 21 CFR 207.57, provide drug listing information for any drug manufactured, repacked, relabeled, or salvaged that has not been previously submitted.
- Submit the date an establishment discontinued the manufacture, repacking, relabeling or salvaging of a listed drug and provide the expiration date of the last lot manufactured, repacked, relabeled or salvaged.
- Submit any material changes to any information previously submitted.
- Submit the date an establishment resumed the manufacturing, repacking, or relabeling a drug previously discontinued.

Who must delist a product and when?

- Under 21 CFR 207.57(b)(2), each registrant must delist their products when the product is no longer in U.S. commercial distribution.
  - For foreign manufacturers, importation is commercial distribution.

- Submit the drug's marketing end date. This date should be the expiration date of the last lot manufactured or distributed.

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How to delist and update drug listing information CDER Direct Live Demo

https://direct.fda.gov/

U.S. Department of Health & Human Services

FDA **CDER** *Direct*
Electronic Submissions Portal

This application is for TESTING only. Any submissions made in this application are not officially recognized by the FDA. Use direct.fda.gov to make official submissions to FDA.

LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I Understand.

LOGIN Forgot your password?

QUICK LINKS

- Register With CDER Direct
- Resources
- Tutorials
- Help Desk
- FAQs

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. *Click here* to create a new account.

If you already have an account, enter your **Username** and **Password**.

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

Browser Compatibility: The CDER Direct portal currently works best with the following browsers:

- Microsoft Edge
- Firefox version 28 and above
- Google Chrome
- Safari 10.0.1 and above

NOTIFICATIONS

Challenge Question!!

How often must a registrant review and update their drug listing information?

a. Once a year
b. Every month
c. Never
d. June and December each year

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Thank You!

Contact us: eDRLS@fda.hhs.gov


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