

How to Delisting/Updating a Product

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Delisting a product



- Create a new version of the most recent accepted submission
- Change the marketing status from “ACTIVE” to “COMPLETED”
- Enter the marketing end date for the product (FDA recommends using the expiration date of last lot produced)
- Submit SPL

This is a **TESTING ONLY** application. [Click here](#) to log into the Production Environment. Any submissions made in the application are not officially submitted to FDA.

COVID-19 Update - As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product. Additional information can be obtained after logging in. (Not applicable to 563B outsourcing or compounding facilities)

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

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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 Internet Explorer 8 (IE8) and above
- Firefox version 28 and above

NOTIFICATIONS

12-SEP-14 **new!** Welcome to CDER Direct!

Updating a Previous listing



- Create a new version of the most recent accepted submission
- Do not change the Set ID!
- A new Root ID and version number will generate automatically

- Modify all listing data elements and labeling information as appropriate
- Submit SPL

Contact Us!

- eDRLS Helpdesk: edrls@fda.hhs.gov
- CDER Direct Helpdesk: CDERdirect@fda.hhs.gov
- Thank you

