

How to Create a Kit Listing

Troy Cu

Technical Information Specialist
Office: CDER/OC/OU DLC/DRLB

What to include in kit Listing

- **NDC – for overall kit and individual parts**
- **Establishments – for overall kit manufacture**
- **Content of Labeling –for overall kit and parts as appropriate**
- **Parts – for all drug and non-drug (e.g., device) parts**
- **Packaging – for overall kit and quantity of each part within the kit**

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 503B 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

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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 38 and above

NOTIFICATIONS

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

Contact Us!

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

