How to Create a Kit Listing

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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)

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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.

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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 30 and above
Contact Us!

• eDRLS Helpdesk: edrls@fda.hhs.gov

• CDER Direct Helpdesk: CDERdirect@fda.hhs.gov

• Thank you