CDER Direct
503B Product Reporting

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Overview I

- Regulation

  – 503B Registration

  – 503B Product Reporting

- How to submit an Outsourcing Facility Registration and Product Reporting using CDER Direct.

- Common Errors

- Summary

- Related Resources

- Challenge Question

FDA

Overview II

- **The Drug Quality and Security Act**

  – Created a new section 503B in the FDCA

  – A compounder can become an "outsourcing facility"

- **Outsourcing Facility is...**

Overview III

- **Outsourcing Facilities are:**

  – Exempted from FDA approval requirements

  – Exempted from certain labeling requirements

  – NOT exempted from cGMP Requirements

Overview IV

- **Upon Registration, an outsourcer must:**

  - Submit an <u>initial product reporting </u>of all compounded products

  - Must submit in <u>June and December</u>

What to include in PR

- Active ingredient and strength of active ingredient per unit

- Source of the active ingredient <u>and</u> NDC of the source drug or bulk active ingredient

- Dosage form and route of administration

- Package description

- Number of individual units produced

- NDC number of the final product, if assigned

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   Forgot your password?

QUICK LINKS

Create Account

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

NOTIFICATIONS

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

PR Common Errors I

- If the NDC product/item code was previously submitted, then the active ingredient UNIIs and active ingredient strengths must be the same as in the most recent submission for this NDC product/item, except if there is no marketing status other than new or cancelled, Must be a known listed product

- *Translation: If you change the active ingredient or strength, you must also change the Product NDC*

PR Common Errors II

- Ingredient source product item code (source NDC) must have been previously submitted (i.e. must be a known listed product). for Source NDC – 12345-6789

- *Translation: Source NDC must also be listed.*

PR Common Errors III

- The Set id must not be associated with any top level product with a different NDC Labeler Prefix

- *Translation: Keep using the same SetID for updated new versions of product report.*

PR Common Errors IV

- If the NDC product/item code was previously submitted, then the product name must be same as in the most recent submission for this NDC product/item code

- *Translation: If you change the product name, you must change the Product NDC.*

Summary I

- Required to submit product reporting in June and December

- Source NDC is REQUIRED for all source drug ingredients

- Prepare ahead of time to get ingredient NDCs and verify listing status

- Use of NDC is the most efficient method of source identification.

Summary II

- We encourage the assignment of NDCs to all compounded drugs

- One labeler code is used for all products compounded at the same location and the firm should assign different product and package codes within the rules for assigning NDCs to ensure differentiation between drugs.

Summary III

- Each qualified active ingredient source provides a unique drug listing (NDC)

- NDC (drug listing for final 503B product) assignment is optional

  - Products with same formulation but different active ingredient source must have a different Product NDC

Summary IV

- Unique final product NDCs may help improve quality consistency, risk evaluation, and targeted response

- Changing the active ingredient sources may result in product, supply chain, performance, risks, or quality differences

- Reporting system accepts different quantities for each source NDC change

Summary V

- A compounded drug that uses more than one source for its active ingredient should be reported separately for each ingredient source and provide the specific number of packages produced from that source.

Helpful Resources I

- **The Drug Quality and Security Act: Human Drug Compounding Outsourcing Facility:**
http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm

- **Guidance for Industry: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):**
http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424303.pdf

- **Data Files for Unfinished Drugs are available on FDA's National Drug Code (NDC) Directory:**
https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm

Helpful Resources II

- **Electronic Drug Registration and Listing Instructions:**
  https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

- **Human Drug Compounding Website:**
  https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

- **503B Compounding Dashboard:**
  http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm

Helpful Resources III

- **National Drug Code Directory:**
https://www.fda.gov/drugs/informationondrugs/ucm142438.htm

Data Files for Unfinished Drugs

- NDC Unfinished Drugs Database File (Zip Format)
Last updated:9/21/2020   .

- NDC Unfinished Drugs Excluded Database File (Zip Format)
Last updated:9/21/2020

Helpful Resources IV

https://www.accessdata.fda.gov/scripts/cder/outsourcingfacility/index.cfm

Outsourcing Facility Product Report search

Search the Outsourcing Facility Product Report database

| Select Reporting Year | ⌄ |

| Select Type | ⌄ |

| Enter at least three characters |

Search **Clear**

Challenge Question

FDA

Which of the following are TRUE statements related to 503B Product Reporting?

A. A compounded drug that uses more than one source for its active ingredient should be reported separately for each ingredient source

B. NDC assignment is optional

C. Source NDC is REQUIRED for all source drug ingredients

D. All above

Contact Us!

- **eDRLS Helpdesk:** edrls@fda.hhs.gov

- **CDER Direct Helpdesk:** CDERdirect@fda.hhs.gov

- **Compounding Helpdesk:** Compounding@fda.hhs.gov