CDER Direct
503B Product Reporting

Troy Cu
Technical Information Specialist
Office: CDER/OC/OUDLC/DRLB

Overview

- 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

Overview

- **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

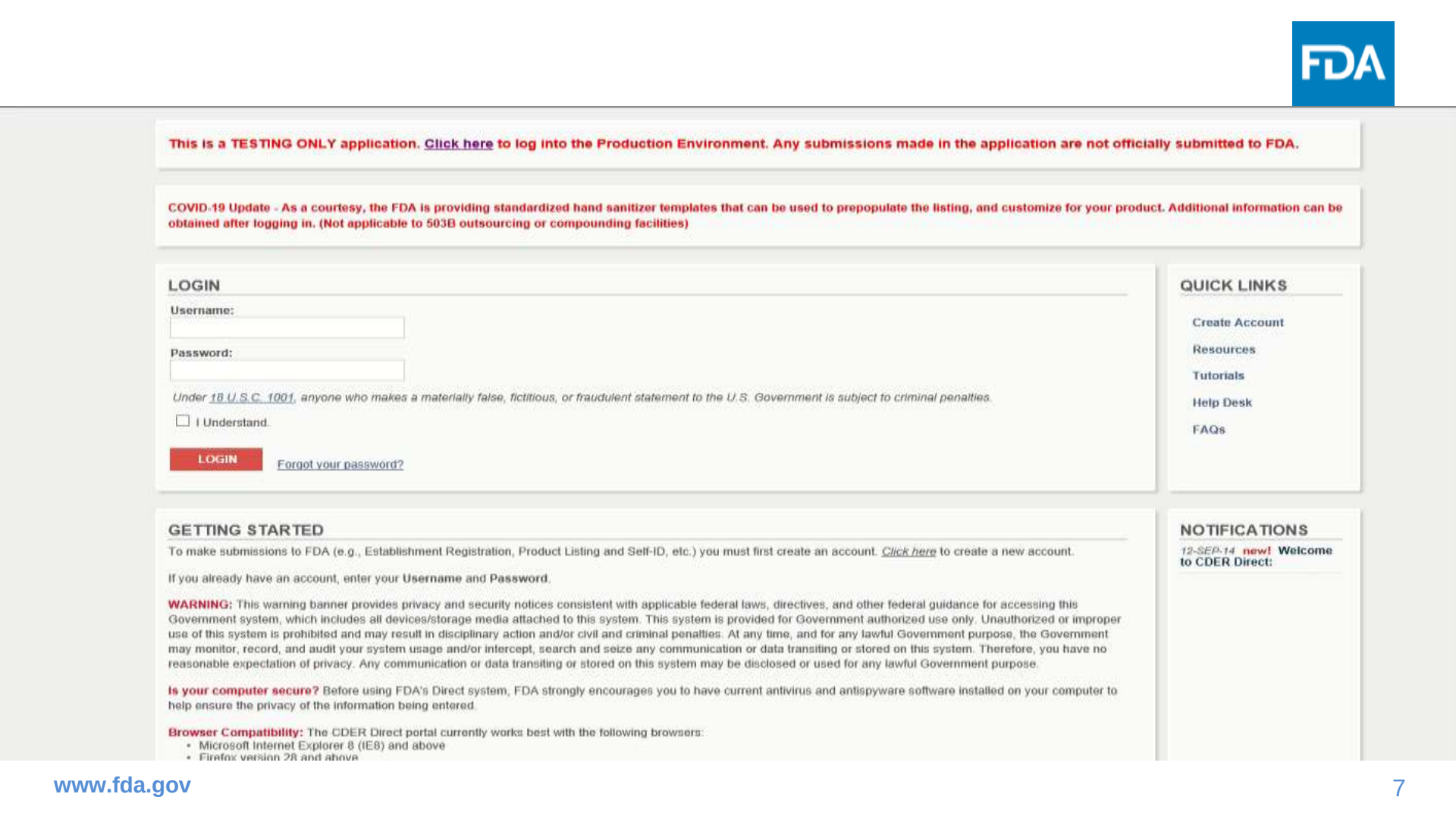
- **Outsourcing Facilities are:**
  - Exempted from FDA approval requirements
  - Exempted from certain labeling requirements
  - NOT exempted from cGMP Requirements

Overview

- **Upon Registration, an outsourcer must:**
  - Submit an initial product reporting of all compounded products
  - Must submit in June and December

What to include in PR

- Active ingredient and strength of active ingredient per unit
- Source of the active ingredient and 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


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
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:

Draft deleted successfully.

Home > Product Listing and Reporting

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- WDD/3PL

PRODUCT LISTING AND REPORTING

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.

GO | ACTIONS | SEARCH PRODUCT | CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED	
DRAFT	cd4e297e-a6e5-516c-e053-2a95af0a2738	cd4e297e-a6e6-516c-e053-2a95af0a2738	-	1	HUMAN COMPOUNDED DRUG LABEL		DETAILS	Troy Cu	01-OCT-2021 12:36:40	-
DRAFT	cd2952ae-52cb-6310-e053-2a95af0a3cd5	cd2952ae-52cc-6310-e053-2a95af0a3cd5	-	1	HUMAN OTC DRUG LABEL		DETAILS	Troy Cu	29-SEP-2021 16:51:54	-
DRAFT	cc222f1c-6eef-eb74-e053-2995af0aa128	cc222f1c-6ef0-eb74-e053-2995af0aa128	-	1	HUMAN OTC DRUG LABEL	Kit Demo	DETAILS	Troy Cu	29-SEP-2021 16:37:19	-
DRAFT	c3abcbc2-07c0-401c-b052-5db24798b09e	ccad0eba-981b-4a5c-e053-2995af0a9e98	-	4	HUMAN OTC DRUG LABEL	DRUG FACTS	DETAILS	Troy Cu	29-SEP-2021 15:38:30	-
DRAFT	cd281f7d-6917-a2ad-e053-2a95af0aa5c1	cd281f7d-6918-a2ad-e053-2a95af0aa5c1	-	1	HUMAN OTC DRUG LABEL		DETAILS	Troy Cu	29-SEP-2021 15:20:54	-
SUBMISSION ACCEPTED	ccffc732-6a15-15a9-e053-2a95af0ab543	ccffadce-3a9f-6869-e053-2995af0afabf	-	1	HUMAN OTC DRUG LABEL		DETAILS	Troy Cu	27-SEP-2021 15:05:35	-
DRAFT	cc0d7b26-27cd-b81e-e053-2995af0a933c	cc0d7b26-27ce-b81e-e053-2995af0a933c	-	1	HUMAN COMPOUNDED DRUG LABEL	Demo	DETAILS	Troy Cu	21-SEP-2021 19:56:08	-

1 - 7

PR Common Errors

- 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

- 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

- 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

- 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

- 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

- 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

- 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

- 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

- 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

- **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

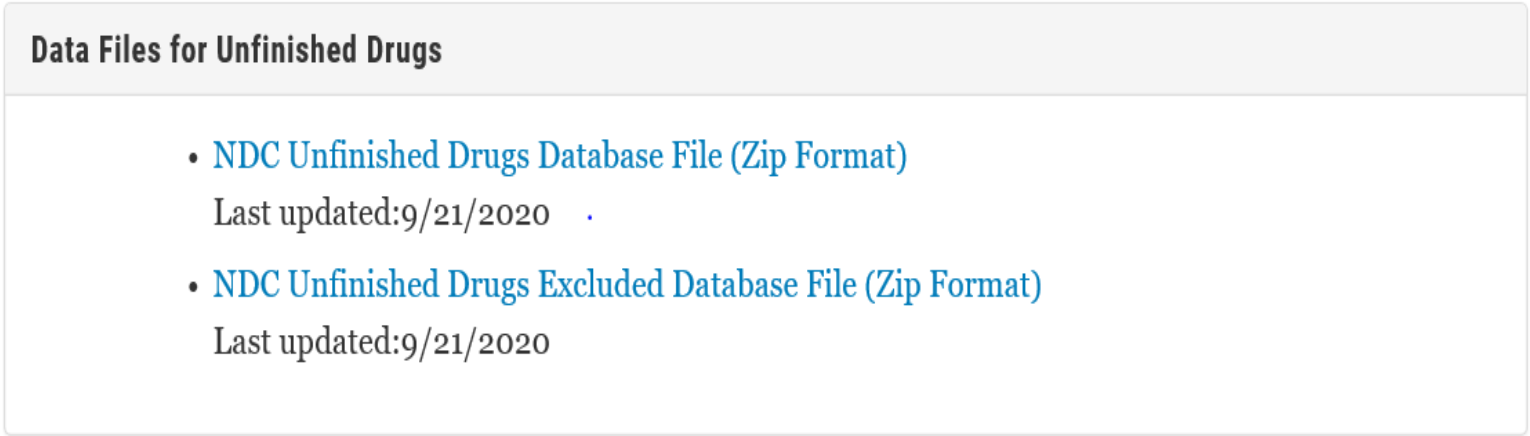
- **Electronic Drug Registration and Listing Instructions:** https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

- **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

- **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

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

Challenge Question

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