Registration and Listing Deficiency Letters

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FDA/CDER/OC/OUDLC/eDRLB

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Agenda

- Brief overview of our compliance program
- What if I get a deficiency letter - What are the important points and what needs to be done
- Case example - A drug listing deficiency
- Live demo: How to revise a submission
- Manual overrides -- Do’s and Don’ts
- Labeler and registrant responsibilities
- Resources
- Questions

Registration and Listing Compliance Program

- When inaccuracies are found in the registration or listing data:
  - A compliance case is opened and a registration or listing deficiency letter is sent
    - This letter is emailed to the registrant or labeler contact
    - Firm has 30 days to make corrections

What if I Get a Deficiency Letter?

- **DO NOT IGNORE IT**
- Read the error statement -- located in opening paragraph
- Review the table -- located at the bottom of letter
  - Table with details usually in a listing deficiency letter
- Follow the instructions -- located in the body of the letter

Making Corrections

- Access the existing SPL file(s), **keep the same SET-ID**
- Make any necessary changes (fix the deficiency identified in the letter)
- Submit

https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm.

Automated Error Messages

- Can occur when there are data discrepancies between the initial submission and the revised version
  - Technical errors
  - Compliance errors
- Some will require a correction for submission to pass
- Some will require a manual override before the submission is accepted

Manual Override Requests

- Email edrls@fda.hhs.gov: List of errors and Core ID or Submission ID
- If approved, send CDER's approval to the SPL Coordinator at spl@fda.hhs.gov

Case Example - “Wonderdrug”

- Compliance officer detects an error in the listing of WonderDrug of mismatched strength of active ingredient
- Opens a compliance case
- Sends a *drug listing deficiency letter*
  - To the labeler contact of WonderPharma

Case Example – “Wonderdrug”

Listing Deficiency letter to WonderPharma

Dear John Doe,

Based on the Food and Drug Administration's (FDA), Drug Registration and Listing Staff quality-control activities, “**we have found that your listing submission includes a mismatched strength of active ingredient”**. The specific National Drug Code(s) (NDC) and associated error(s) or omission(s) that we identified are itemized at the end of this letter.

Case Example- “Wonderdrug”

- Check the table at the bottom of the letter

NDC	Proprietary Name	Issue
55555-333	Wonderdrug	The strength of the active ingredient does not match between the labeling and the listing SPL. The strength in the labeling is found to be 2000 mg while the strength listed in the SPL is 200 mg.

Case Example- “Wonderdrug”

WONDERDRUG- wonderdrug tablet
Wonderpharma

Active ingredient in each tablet

Wonderdrug 2000mg

PURPOSE

Pain reliever/ fever reducer

Dosage & Administration

Dosage

Warnings

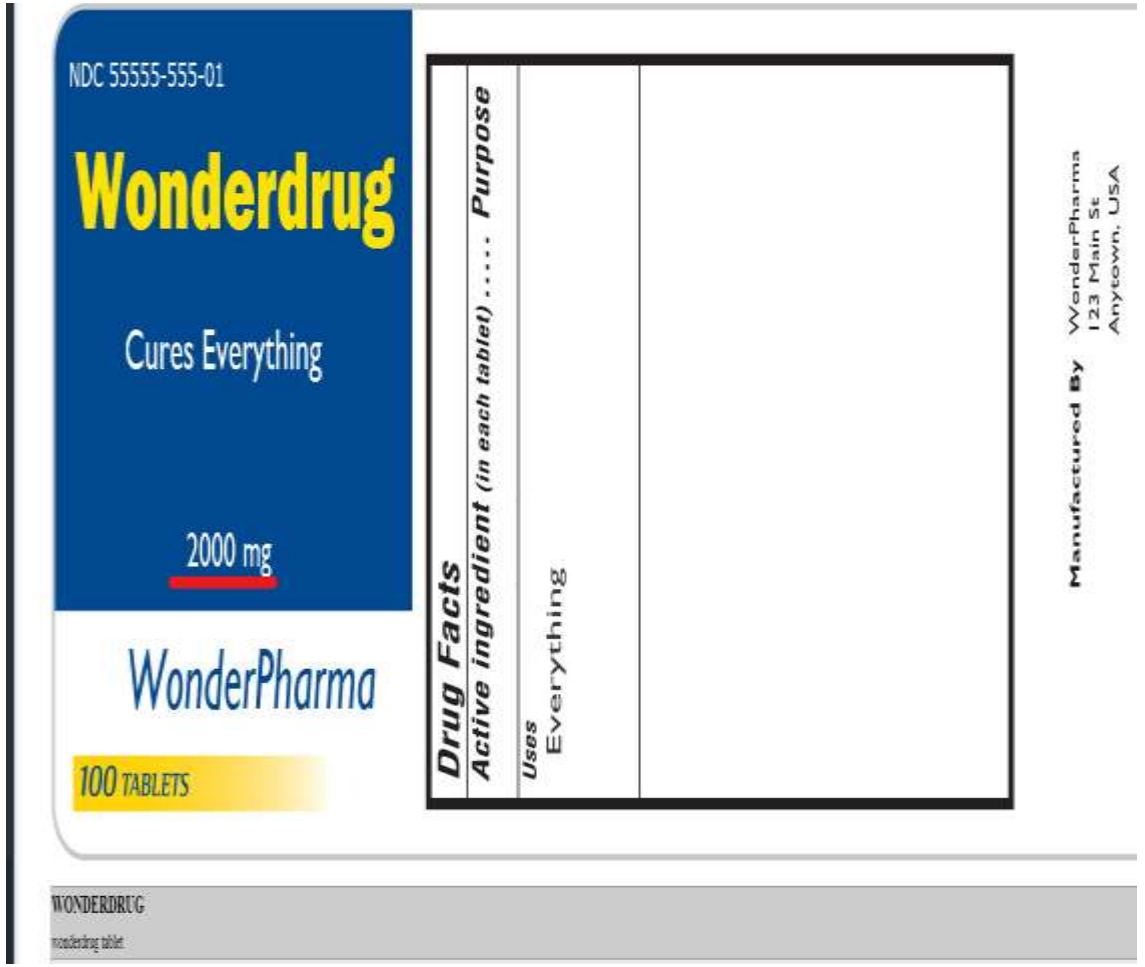
Warnings

Inactive Ingredients

WATERMELON SEED OIL

Indications & Usage Sections

Use to cure anything



Case Example – “Wonderdrug”

WONDERDRUG

wonderdrug tablet

Product Information			
Product Type		Item Code (Source)	55555-333
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	200 mg

Inactive Ingredients	
Ingredient Name	Strength
WATERMELON SEED OIL (UNII: L33J06UQTT)	0.25 mg

Product Characteristics			
Color	blue	Score	no score
Shape	CLOVER	Size	10mm
Flavor		Imprint Code	
Contains			

Packaging			
#Item Code	Package Description	Marketing Start Date	Marketing End Date

Case Example- “WonderDrug”

- Revision of the listing submission using the CDER Direct software tool

Electronic Submissions Portal

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.

NOTIFICATIONS

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

Electronic Submissions Portal

MISSIONS
SUBMISSION TYPE)
NHRIC Labeler Code Request
blishment Registration
FA Self-Identification
uct Listing and Certification

AGE ACCOUNT
User Profile
ge Users

ID-19
pplicable to 503B outsourcing or
ounding facilities)
Hand Sanitizers you first need to
t a Labeler Code Request and an
ishment Registration. When these
been completed you can then submit
duct Listing. Please view the user
s below for each submission type.
er Code Request

ALL SUBMISSIONS

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

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION FAILURE	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	cd3e60e2-ba7b-73cf-e053-2a95af0aaaed	-	3	HUMAN OTC DRUG LABEL	Tasneem Hussain	30-SEP-2021 17:49:10	
SUBMISSION ACCEPTED	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	ccaf9d80-ec93-dfac-e053-2995af0acc2a	cd8641903752.5192760483@direct	2	HUMAN OTC DRUG LABEL	Tasneem Hussain	23-SEP-2021 15:37:09	
SUBMISSION ACCEPTED	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	cc22b97b-2423-2903-e053-2a95af0a5e0c	cd2807496315.8139402756@direct	1	HUMAN OTC DRUG LABEL	Tasneem Hussain	16-SEP-2021 15:41:09	

1 - 3

Electronic Submissions Portal

Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back in to the CDER Direct Electronic Submissions Portal. You will also receive an email from FDA when the processing is complete.

MISSIONS
SUBMISSION TYPE)
NHRIC Labeler Code Request
blishment Registration
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GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION FAILED	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	cd3d9c9b-d348-81de-e053-2995af0a1dd3	cd2086715349.8064721539@direct	3	HUMAN OTC DRUG LABEL	Tasneem Hussain	30-SEP-2021 17:07:09
SUBMISSION ACCEPTED	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	ccaf9d80-ec93-dfac-e053-2995af0acc2a	cd8641903752.5192760483@direct	2	HUMAN OTC DRUG LABEL	Tasneem Hussain	23-SEP-2021 15:37:09
SUBMISSION ACCEPTED	cc22d53d-c2e9-64fb-e053-2a95af0a0b94	cc22b97b-2423-2903-e053-2a95af0a5e0c	cd2807496315.8139402756@direct	1	HUMAN OTC DRUG LABEL	Tasneem Hussain	16-SEP-2021 15:41:09

1 - 3

Case Example “WonderDrug”

- As was seen in the demo:
- A change made to a key element in the SPL – resulted in a compliance error
- 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. [3.2.1.32]
  - In this case you are making a necessary correction due to the listing deficiency letter
- This compliance error **will** require a manual override

Manual Override Do's and Don'ts

- DO --- Provide a Core ID/ submission ID when requesting a manual override or requesting a review for approval of a manual override,
- DO --- Make sure that core IDs/submission IDs are prominent and not buried in e-mail traffics
- DO --- Provide the ID as text in the body or subject line of an e-mail message to afford the ability to copy the ID instead of retyping the ID
- DO --- Make sure that the request is very clear and does not contain confusing or contradictory details
- DO --- Manual override request e-mail messages with multiple core IDs/submission IDs are preferred to be formatted as one core ID/submission ID per manual override request

Manual Override Do's and Don'ts

- DO NOT--- include a core-id/submission-id as part of a screen image as these will not be accepted
- Do NOT--- Add barely legible images of screens, etc. included as supportive material because your request for manual override may not be accepted
- Do NOT--- Provide inaccurate or incomplete data at time of request
- Do NOT--- Have discrepancies in stated error and the number of issues in the actual error messages
- DO NOT--- Provide a partial CORE-ID or Submission-ID
- DO NOT --- Reference a previous message without including that message as an attachment
- DO NOT --- Send multiple requests
- DO NOT--- Skip the subject line and do not have a subject line which is not related to the message in the content

ALL these DO NOTs will only cause delays in response to your request

Case Closed

The case will only be closed when all revisions are completed, and the new data is accurate

Labeler and Registrant Responsibilities

- "Failure to properly list a drug product as required by section 510(j) of the Act is prohibited and will render a drug misbranded, *21 U.S.C. 331(p), 352(o).*"

- "Non-delivery of the email notification due to outdated contact information will not relieve the firm from its registration and listing obligations. "
  - 21 CFR 207.35 Contact information must be updated within 30 days of any change
  - FDA uses this contact information for registration and listing related correspondence
- "This is not an all-inclusive letter containing all listing errors associated with your products."
- <u>"It remains your responsibility to determine whether your firm and its products are in compliance with applicable laws."</u>

Good Resources to Review

- Electronic Code of Federal Regulations (eCFR)
- Electronic Drug Registration and Listing Instructions | FDA
- Electronic Registration and Listing Compliance Program | FDA
  - Strength conversion in drug listing
- SPL Implementation Guide and Validation Procedures: https://www.fda.gov/media/84201/download

Questions

Thank you

edrls@fda.hhs.gov.