CDER Direct Product Listing

Julian Chun, Pharm D., MBA

Tasneem Hussain, Pharm D.

Electronic Drug Registration and Listing Workshop
October 5, 2017

Overview

- The “Who”
- The “When”
- The “What”
- Demo: listing submission of “Wonder Drug”
- Steps for updating a previously submitted file and Delisting
- Helpful hints and common errors
- Summary

Product Listing : “Who”

- Unless exempt, **ALL** registrants must submit listing information for all drugs manufactured, repacked, and relabeled or salvaged for commercial distribution
- Contract Manufacturer Organizations (CMO)
  - CMO must list under their own labeler code
  - CMO must also list for PLDs, using the PLD’s labeler code
- Private Label Distributors (PLD) do not register but may choose to list their own label drug products as authorized agents for the CMO

Product Listing : “When”

- Initial:
  - Listing information must first be submitted within 3 days of the initial registration of the establishment
- Updates:
  - Review and update any changes to the listing information every June and December or as soon as possible
- Annual listing certification! *NEW*
  - “Blanket No Change Certification”
  - See Session 4: “Listing Certification”

Product Listing : “What”

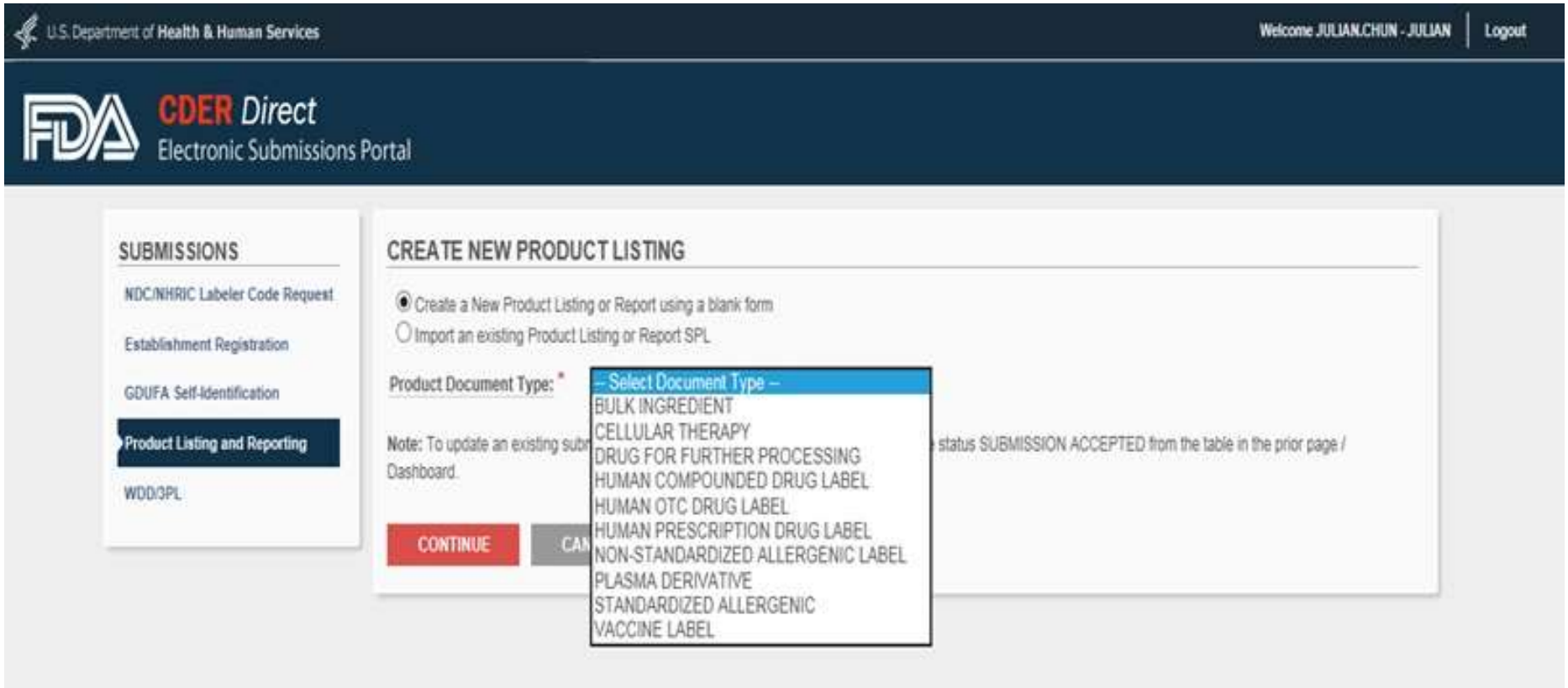
- Proprietary and non-proprietary name
- The name and quantity of the active ingredient(s)
- Inactive ingredient(s) *NEW*
- Route(s) of administration
- Marketing information
  - Category
  - Start and end dates
- DEA Schedule

Product Listing : “What” Cont.

- Package size and type
- Labeling
  - Content of labeling
    - Package insert
    - JPEG of carton label
- Application number or monograph citation as appropriate
- Name of the establishment who manufactures the listed drug along with the type of operations performed

CDER Direct Demo

Wonder Drug



Status After Submission

- Message on the screen:
  - Your submission has been sent to FDA for additional validation and processing Check back on the status of your submission after a few minutes by refreshing the page or logging back in to the portal
- You will also receive an email from FDA when the processing is complete.
  - You will be able to click and check the status of the submission

Updating a Previous Listing

- Create a new version of the most recent submission
- Do not change the Set ID, retain the original one from the previous version
- A new Document ID / Root ID will automatically generate for you
- The appropriate date and a new version number (generally, one number higher than the previous submission) will also generate automatically
- Modify all listing data elements and labeling information as appropriate
- Submit

Delisting a Product

- Create a new version of the most recent submission
- The SET ID will again remain the same
- A new Document ID / Root ID will automatically generate for you
- The appropriate date and a new version number will also generate automatically
- Change the marketing status from “Active” to “Complete”
- Enter the end marketing date for the product
  - Date can be in the future
    - Expiration date of last lot in distribution
- Submit

Helpful Hints

- Word → XML or PDF → XML may cause formatting issues
  - E.g., “Wonderdrug’s mechanism of action” → “Wonderdrug?s mechanism of action”
- Copy and paste into Notepad. Copy from Notepad into CDER Direct
- Remember to keep the Set ID “Set”

Common Errors

- Incorrect strength
- Incorrect proprietary name
  - Generic listings should use generic name for both proprietary and non-proprietary names
- Incorrect carton label (Primary Display Panel)
  - Uploading wrong image
- Un-registered DUNS for manufacturer

Summary

- Remember to check the rules and regulations for the “Who” “What” and “When” of drug listing
- Remember what information needs to be updated and when it should be submitted
- Remember to delist when no longer in commercial distribution
- Remember to double check the listing data elements to avoid errors leading to inaccurate information available in public databases
- If you need any assistance from our Drug Registration and Listing Staff or have technical issues please contact us

Questions?

- Technical questions:
  - CDERDirect@fda.hhs.gov
- Regulatory questions:
  - edrls@fda.hhs.gov

Thank you!


FDA
U.S. FOOD & DRUG
ADMINISTRATION