# CDER Direct Product Listing

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# Overview

- The “Who”
- The “When”
- The “What”
- Live Demo: Listing submission
- Updating listings and Delisting
- Helpful hints and common errors
- Summary

# Product Listing : “Who”

- Unless exempt, **ALL** registrants must list all drugs manufactured for commercial distribution
- Registrants that manufacture a product at more than one of its own establishments may submit under a single listing
  - All establishments must be identified within the listing
- Contract manufacturers (CMO) must list under their own labeler code
  - CMO who manufacture for private label distributors (PLD) must also list for PLDs, using the PLD’s labeler code
  - PLDs may list their own products as an authorized agent

# 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, but preferably as soon as possible
- Annual listing certification
  - Accepted updates to the listing certifies your listing for the calendar year and the next calendar year

# Product Listing : “What”

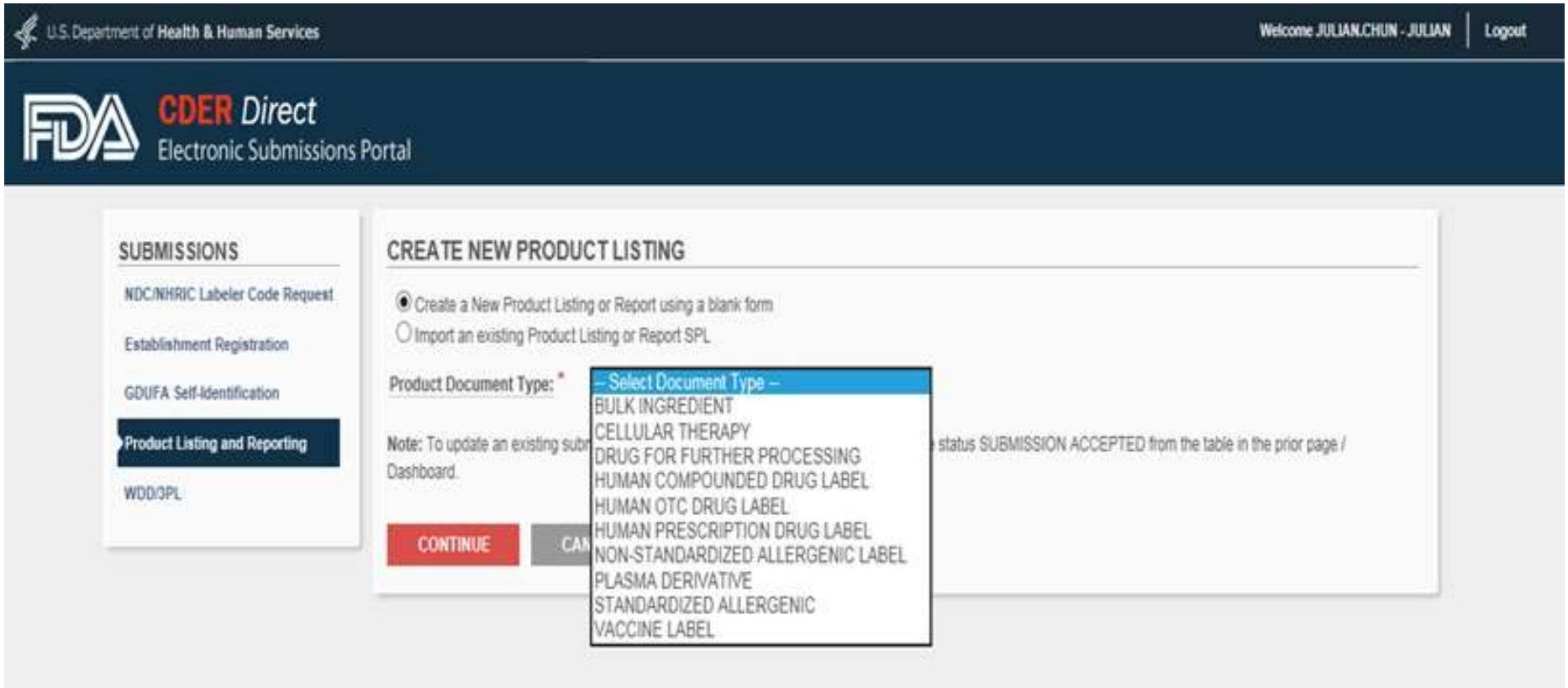
- Proprietary and non-proprietary name
  - If no brand name, use generic name for both fields
- The name and quantity of the active ingredient(s)
  - Name and quantity of active moiety (if applicable)
- Inactive ingredient(s)
- DEA Schedule

# Product Listing : “What”

- Content of labeling
  - Package insert
  - JPEG of carton label
- Marketing Category
  - Application number, Monograph citation, Unapproved, etc.
- Name of the establishment who manufactures the listed drug along with the type of operations performed

# CDER Direct Demo

## Wonder Drug Liquid



# 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 accepted submission
- Do not change the Set ID!
- A new Root ID will automatically generate
- The 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
- Keep the same SET ID
- A new Root ID will automatically generate
- The date and a new version number will also generate automatically
- Change the marketing status from “Active” to “Completed”
- Enter the end marketing date for the product
  - e.g., 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 first. Copy from Notepad into CDER Direct

➢ Set ID = same throughout life of listing

➢ Root ID / Document ID = refers to versions

➢ Submission ID / Core ID = each submission (failed or accepted) – needed for manual overrides (starts with “c”)

# Summary

- Have a standard operating procedure or system in place to verify the accuracy of listings at least twice a year
- Remember to delist when no longer in commercial distribution
- EDRLS Toolkit
- **Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S. and their representative labeling**
- **Listing data is also used by the public and other organizations in academia and industry**

# In a Nutshell….

WE ALL NEED THIS INFORMATION

TO BE ACCURATE, COMPLETE AND

UP TO DATE!

# Questions?

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

Thank you!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