# Basic Framework for Reporting

**Jennifer Highland**
Operations Research Analyst
OPQ Office of Quality Surveillance
CDER | US FDA

FDA Webinar – Sept. 8, 2022

# Outline

- Who is required to report?
- What types of drugs should be reported?
- Report submission process
- Data elements to be reported

# Who is required to report? (1 of 2)

- Establishments registered with FDA under section 510 of the FD&C Act
  - Report human drugs under NDCs (National Drug Codes) of both registrant and PLD (private label distributor) labeler codes
  - Report what registrant manufactured, including contract manufacturers
  - Authorized agent may submit a report on a registrant's behalf

# Who is required to report? (2 of 2)

- To simplify reporting, FDA has limited reporting to the following business operations:
  - MANUFACTURE
  - API MANUFACTURE
  - REPACK
  - RELABEL
  - TRANSFILL
  - POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION

# What types of drugs should be reported?

- All listed drugs, except for biological products or categories thereof exempted by an order under section 510(j)(3)(B)
  - Rx and OTC
  - Homeopathic
  - Medical gas
- FDA may issue an order to exempt certain biological products or categories thereof regulated under the Public Health Service Act, if FDA determines that applying such reporting requirements is not necessary to protect the public health.
  - Blood and blood components for transfusion
  - Cell and gene therapy products, where one lot treats a single patient

# Report Submission Process (1 of 4)

- Submitters should create an account in the NextGen Portal (edm.fda.gov) if they do not already have one
- A single account can be used to submit data for any number of establishments
- Multiple reports can be submitted for an establishment

# Report Submission Process (2 of 4)

- Submit separate reports for each calendar year
- Report the number of packages, by NDC, using the package type(s) in the drug listing
  - Single-level packaging or multi-level packaging
- A report can be submitted by:
  - Manually entering data
  - Uploading data from a comma-separated values (CSV) file

# Report Submission Process (3 of 4)

- To enter data manually:
  - Use the portal's interface to provide inputs
  - Use prompts, drop-down boxes, and text boxes
- To upload data from a CSV file:
  - Use the template provided in the portal to create the CSV file
  - Registrants can create their own CSV file, but the format must match the template

# Report Submission Process (4 of 4)

- Reports will be validated using certain data from FDA's Electronic Drug Registration and Listing System (eDRLS)
- The Portal will check for invalid data and display an error message if it identifies data that does not match eDRLS data
- Replacement reports can be submitted if an error is discovered in a previously submitted report

# Data Elements to be Reported (1 of 3)

- Establishment Identity (DUNS)
- Establishment Business Operation
- National Drug Code (NDC)
- Source NDC (For Re-packers and Re-labelers only)

# Data Elements to be Reported (2 of 3)

- Month
- Outermost Package, Quantity Released
- Outermost Package, Quantity Distributed (Non-U.S.)
- Outermost Package Type

# Data Elements to be Reported (3 of 3)

- Innermost Package, Quantity Released
- Innermost Package, Quantity Distributed (Non-U.S.)
- Innermost Package Type
- Market Unknown

# Summary

- Registrants with listed products, including contract manufacturers, are required to report
- Amounts for all listed drugs should be reported by NDC and business operation for each calendar year
- Portal will accept CSV file or manual entry
- Overview of data elements


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