Drug Amount Reporting for Listed Drugs

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Everyone deserves
confidence in their *next*
dose of medicine.
Pharmaceutical quality assures the
availability,
safety,
and efficacy
of *every* dose.

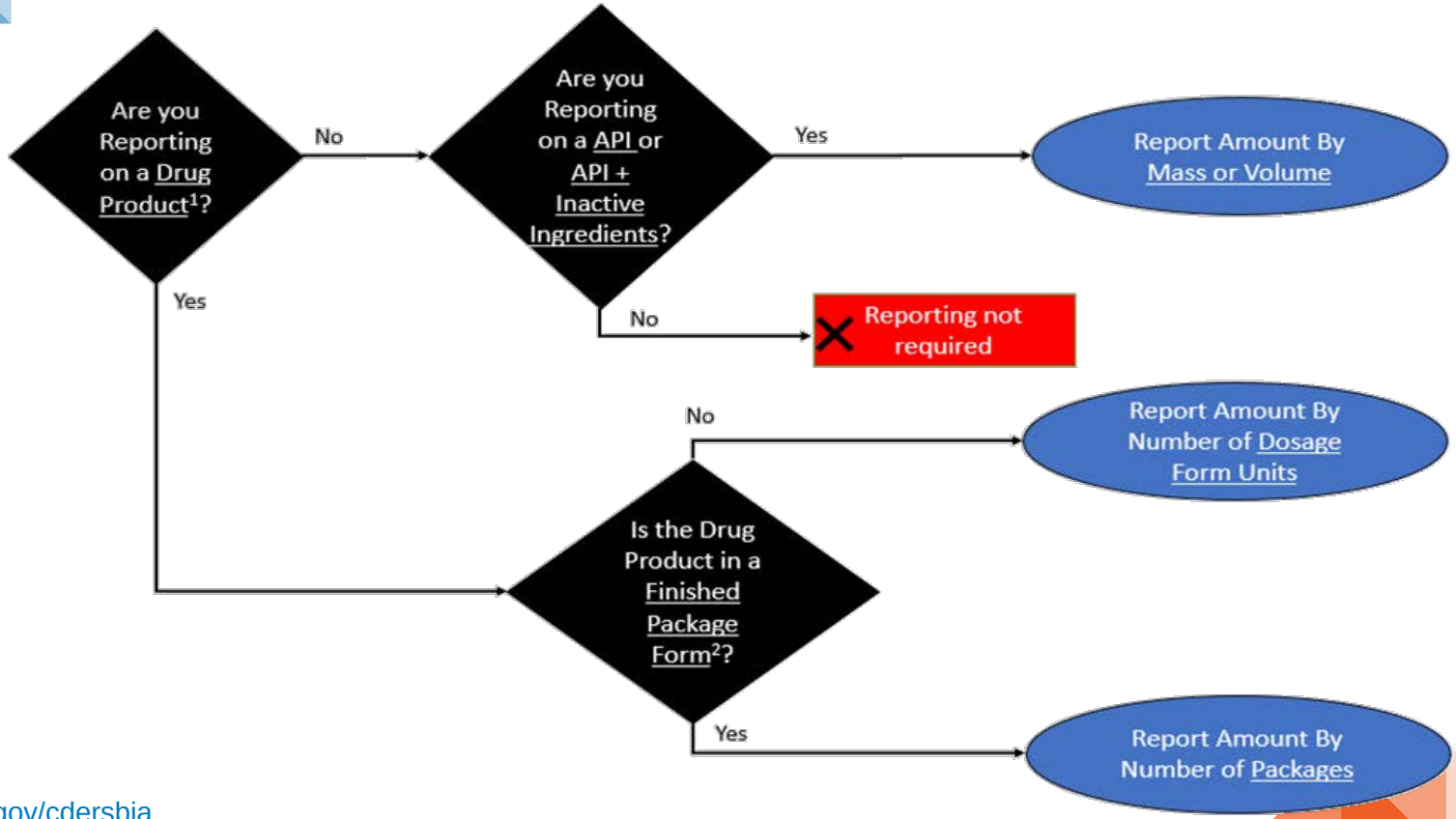
Learning Objectives

- Review key features in the final guidance
- Discuss report submission structure
- Share tips for successful data upload using CSV file

FDA Implements Final Guidance

- Updated time frame for submitting report
- Clarified reporting requirements across the drug supply chain
- Clarified reporting of API activity data
- Improved portal validation

New Report Submission Structure



Data Elements: API or API + Inactive Ingredients Data

- Establishment DUNS
- Business Operation
- NDC
- Amount Per
- Mass/Volume
- Unit of Measure
- Activity (Unit of Measure)
- Average Activity
- Minimum Activity

Data Elements: Drug Product not in Finished Package Form

- Establishment DUNS
- Business Operation
- NDC
- Source NDC
- Amount Per
- Quantity Manufactured
- Quantity Distributed (Non-U.S.)
- Dosage Form Units
- Intended to Fulfill 21 CFR 314.81

Data Elements: Drug Product in Finished Package Form

- Establishment DUNS
- Business Operation
- NDC
- Source NDC
- Amount Per
- Outermost Quantity Manufactured
- Outermost Quantity Distributed (Non-U.S.)
- Outermost Package Type
- Innermost Quantity Manufactured
- Innermost Quantity Distributed (Non-U.S.)
- Innermost Package Type
- Intended to Fulfill 21 CFR 314.81

Tips for successful data upload using CSV file

1) Use correct template and read instructions
2) Use spreadsheet application to populate the CSV file
3) Save file as CSV extension
4) Open saved CSV file in a word processing application to check for problems, like missing leading zeros, rows with only commas “,,,,,,”

Challenge Question

Which of the following statements is NOT true?

A. Reports for Calendar year 2024 should be submitted no later than March 31, 2025

B. API amount is reported by mass or volume

C. Contract manufacturers are not required to submit drug amounts

D. Report structure for drug amount is based on drug type and packaging

Resources

- Guidance Document - Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act
- Technical Conformance Guide - The Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide
- Reference Guide for Reporting Amount of Listed Drugs and Biological Products
- CDER NextGen Portal
- CDER NextGen Portal Account Signup

Questions?

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