

# 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

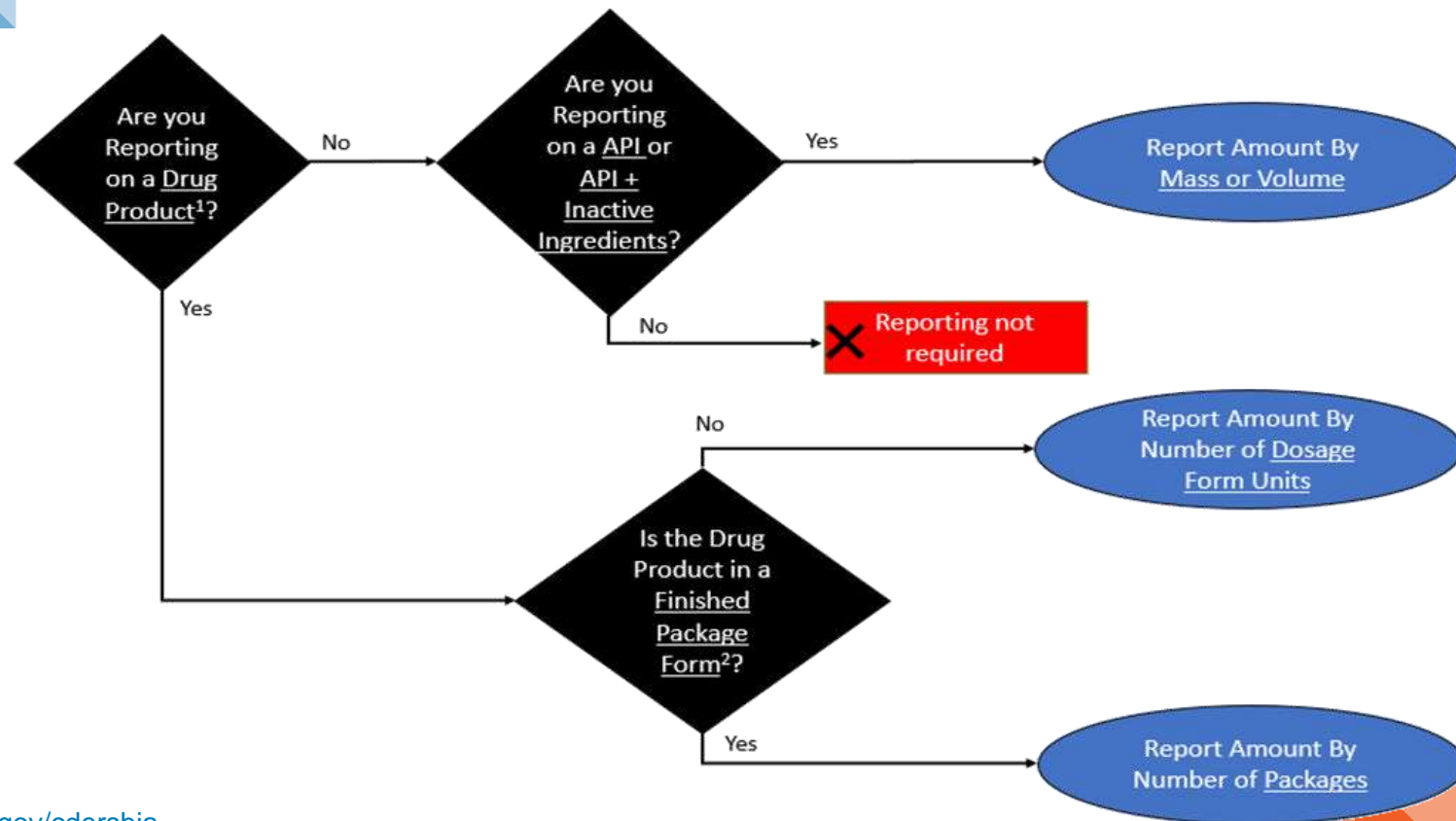


- Review key features in the final guidance
- Discuss report submission structure
- Share tips for successful data upload using CSV file

# 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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