Opening Remarks
Drug Amount Reporting

Jennifer Forde
Regulatory Counsel
Office of Regulatory Policy
CDER | US FDA

Reporting Drug Amount Under Section 510(j)(3) of the FD&C Act –
September 8, 2022

Opening Remarks

- Importance of drug amount reporting data
- Public comments
  - Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act: FDA-2021-D-1031
  - Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide: FDA-2017-D-6821

Opening Remarks (cont.)

- Drug amount data received via the NextGen Portal
- Inquiries received at drugamountreporting@fda.hhs.gov
- Overview of today's presentations (see agenda for details)

Drug Amount Reporting Regulatory Background

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Section 510(j)(3) of FD&C Act

- Each person who registers with FDA under section 510 of the FD&C Act with regard to a drug must
  - report to FDA annually
  - on the amount of each listed drug
  - that was manufactured, prepared, propagated, compounded, or processed by such person
  - for commercial distribution

Registrants

- Obligations pertain to registrants of listed drugs
  - Not applicants, unless the applicant is also the registrant
- Includes, but is not limited to, registrants that are:
  - Contract manufacturers
  - Registrants across the drug supply chain

Listed drugs

- Obligations pertain to listed drugs
  - Finished dosage form products, APIs, and other types of listed drugs
- Drugs not required to be listed are not required to be included in a section 510(j)(3) report

Listed drugs (cont.)

- Obligation pertains to listed drugs manufactured, prepared, propagated, compounded, or processed
- Includes repacking and relabeling
- Note regarding business operations of: sterilize, analysis, particle size reduction, salvage

Commercial distribution

- Any distribution of drug, though does not include
  - Investigational use
  - Internal or interplant transfer
- Foreign establishments
  - Does not include distribution of drug not imported or offered for import into U.S.

Commercial distribution (cont.)

- Does not need to be drug in final packaged form
- Can include other listed drugs, such as API
- Does not have to be last registrant in drug supply chain

Timeframes

- Report must be submitted annually
- Calendar year reporting periods
- Recommendations
  - 2020: 2/15/22
  - 2021: 5/16/22
  - Thereafter: 2/15 of following calendar year
- FDA considering comments regarding timeframes

Resources

- CARES Act Implementation
- Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act (Draft Guidance)
- Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide
- NextGen Portal
- DrugAmountReporting@fda.hhs.gov
- EDMSupport@fda.hhs.gov

Summary

- Reporting obligations pertain to registrants of listed drugs
- Key resource: CARES Act Implementation
- Reports must be submitted annually

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Questions?

Jennifer Forde
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DrugAmountReporting@fda.hhs.gov


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