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Reporting Drug Amounts Under Section 510 of the FD&C Act as an Authorized Agent and CGMP Consultant

September 8, 2022

FDA/CDER Small Business and Industry Assistance Webinar

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Disclaimer

The views reflected in this presentation are solely that of the author and do not reflect the views of the FDA

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Ceutical Laboratories, Inc.
-A Texas Company-

- **SMEs in product formulation, validation, sterilization, quality systems, electronic submissions, etc.**
- **FDA Registered Analytical Labs**
  - **Micro**
  - **Chemistry**
- **CGMP Consultancy (in Dallas, Texas we have a "stable" of consultants)**

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Topics in this Presentation

- Decoding the Guidance
- Identifying Our Roles and Responsibilities
- General Description of a Few Client and Manufacturing Scenarios
- General Experience of Reporting Drug Volumes in the CDER NextGen Portal
- Challenges
- Recommendations for Industry and FDA

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Decoding the Guidance

- **What's the big picture?**
- **Resources**
  - Draft Guidance
  - Technical Conformance Guide
  - CDER NextGen Process Instructions
  - Appendices and Footnotes
  - There is a ton of info!
  - Client scenarios
  - **SPL Process Team**
    - **Q&A Sessions**
    - **Presentation**

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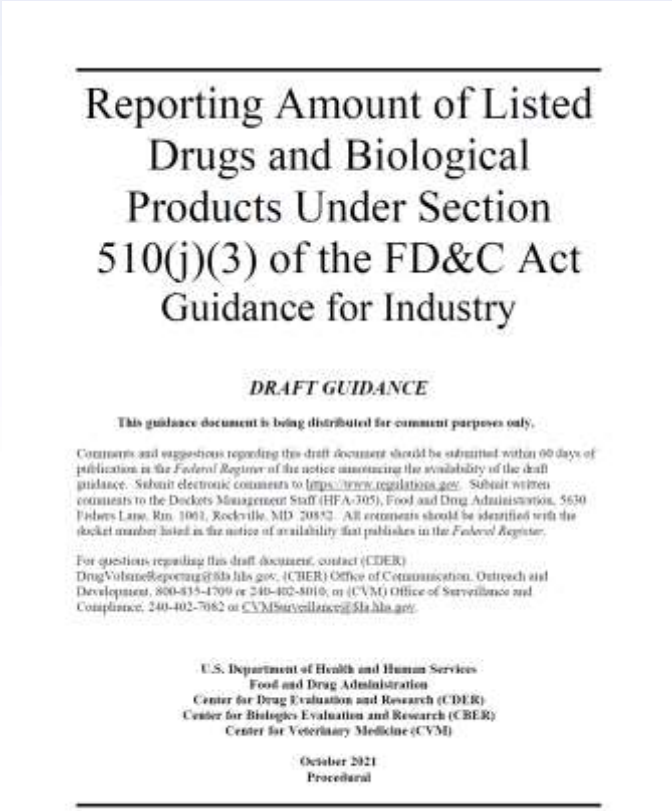
Decoding the Guidance

Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act

- Draft Guidance for Industry
- October 2021
- General who, what, when, where, and why?
- Important footnotes
  - Definitions
    - Released - FDA Guidance for Industry ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (ICH Q7) (September 2016)
    - API, registrant, manufacture, commercial distribution, applicant, unfinished drug, kit
  - CMO should consider using Quality Agreements
- Helpful Q&A section



Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) DrugVolumeReporting@fda.hhs.gov; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CVM) Office of Surveillance and Compliance, 240-402-7982 or CVMSurveillance@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

October 2021
Procedural

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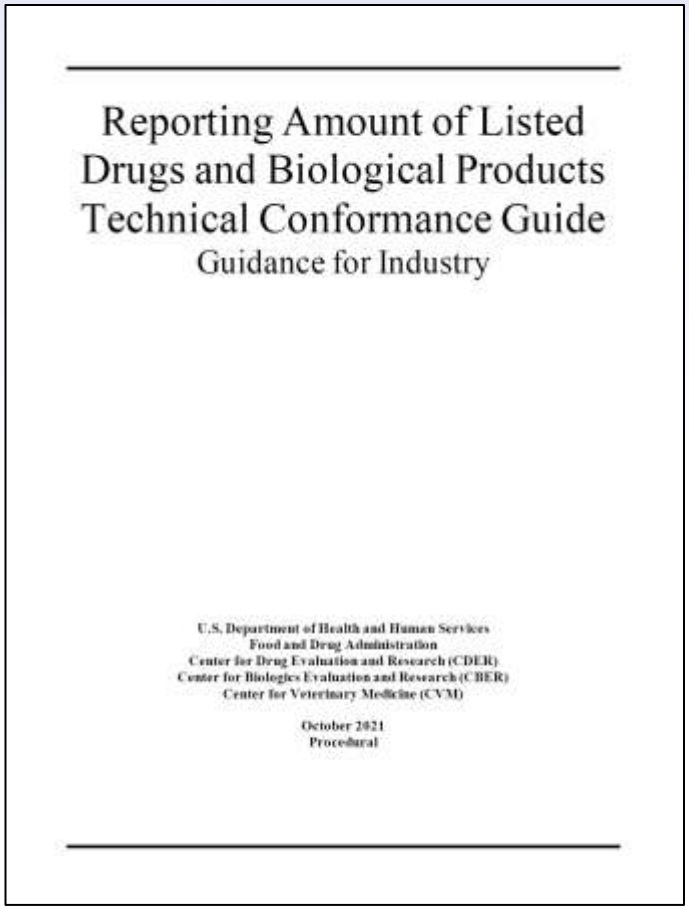
Decoding the Guidance

Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide

- Final Guidance for Industry
- October 2021
- Specifies report content and **how** to submit
- Important footnotes
  - Definitions
    - Relabeling
    - Repackaging
    - Released - FDA Guidance for Industry ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (ICH Q7) (September 2016)
  - Helpful Appendix with Tables
- *Specifies in Section IV.(B)(1)
  - Submitter Type

*If you are not an employee of the reporting establishment or of another organization under or with common control or ownership of the reporting establishment, you should indicate that you are reporting as an **authorized agent**.


Reporting Amount of Listed Drugs and Biological Products Technical Conformance Guide

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

October 2021
Procedural

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Identifying Our Roles and Responsibilities

1. Provide guidance to client teams during the data compilation and submission process

- Client questions fell into **2 Main Categories**
  - Product related questions
  - Reporting responsibility related questions

2. Submit as Authorized Agent

- Establish submission agreement to submit on behalf of client
- Establish CDER NextGen Portal (if not already established)
- Provide adapted CSV Template for client scenario
- Convert client provided data to acceptable format and submit

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General Description of a Few Client and Manufacturing Scenarios

- **Client A** is a manufacturer and owns their own brand
- **Client B** is a brand owner that uses a CMO for the manufacturing operations
- **Client C** is CMO and works with a number of brand owners
- **Client D** is a brand owner that works with a number of CMOs
- **Client E** is a CMO that also owns the brand but contracts out manufacturing processes to another CMO
- **Client F** is a brand owner and a CMO with multiple facilities where manufacturing operations take place, except for those operations that are contracted out to another CMO with multiple facilities
- **Client G** is a brand owner and manufacturer who will use a CMO to fulfill production quota when behind on production numbers
- **Client H** is a CMO who will manufacturer for a larger brand when the larger brand has "overflow production"

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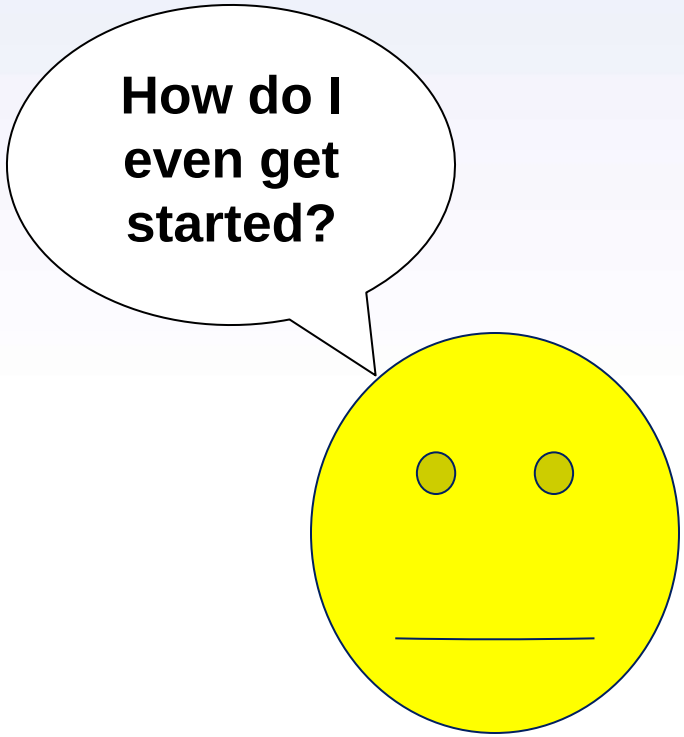
General Description of a Few Client and Manufacturing Scenarios – Part 1

In each case, the FIRST STEP was to request an individual assessment per product SKU **(not certain that it happened but we did our best!)**

- <u>For the Reporting Period:</u>
  - Drug Volume Reporting Data Elements
    - DUNS
    - NDCs
    - 6 Eligible Business Operations – limited to 6 per guidance
    - How many units **<u>released</u>**?

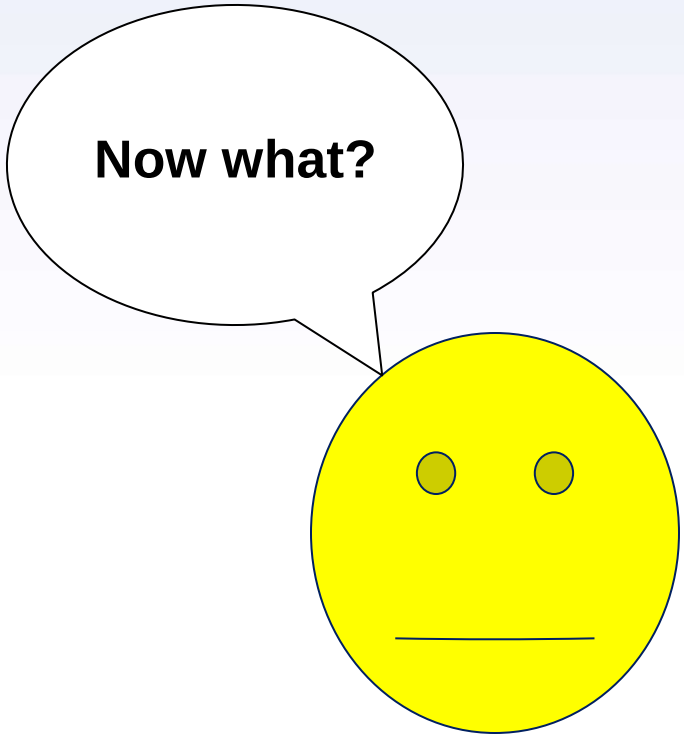


*Our scenarios are limited to Domestic OTC Products. As such, reporting was a fairly simple process…except if there was a CMO involved.☺

General Description of a Few Client and Manufacturing Scenarios – Part 2

In each case, the SECOND STEP was to request an assessment and reconciliation of Registration and Listing information (not certain that it happened but we did our best!)

- **Drug Volume Data and Registration and Listing Status**
  - Was there an NDC listing in place during the reporting period? (General)
  - Reconcile per NDC
  - Use this information to update per each NDC and associated DUNS, Registrant Info
  - Include on next drug volume report
  - This is often more complicated than it at first appears – Quality Agreements can help



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General Experience of Reporting Drug Volumes in the CDER NextGen Portal

- **FDA CDER NextGen Portal Tech Staff** were on the ball!
- To mitigate a possible source of submission errors, we chose to upload CSV files instead of manual entry.

- **Reports from the SPL Process Team have included:**
  - Parse errors
  - Validation errors
  - Trouble adding 9 digit DUNS with leading 0
  - Timing out and having to start over at an earlier step

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Challenges

- Working through "several layers of consultants" and executives.
- Providing guidance to the teams gathering the actual data.
  - Most commonly heard questions
    - Do we report on this?
    - Are we responsible for this?
    - I.e. the guidances were difficult to implement, inherent confounding variable=increasingly complicated supply chains
- Short time frame and many internal Electronic Resource Planning systems may not be set up to generate reports of this data – validation??
- Quality Agreements not in place or not sufficient for managing registration and listing data or volume reporting data.
- Often the NDC number itself serves no internal function at the business, though this has/is changing from the top/down.

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Recommendations

- **Industry**
  - Actively manage registration and listing data, it's not a "one and done"
  - Reconcile NDC listings per registrant at regular intervals
  - Map appropriate internal material/product code to the appropriate NDC product code – suggest validation
    - ERP
    - Spreadsheet
    - However this gets done at your place of business
  - Quality Agreements
    - Very important for increasingly complicated supply chains
    - In addition to the CGMP components of Quality Agreements
      - Manage registration and listing
      - Manage drug volume reporting

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Recommendations

- **FDA**
  - "Help" Industry with Quality Agreements, thank you for the November 2016 Guidance
  - Timeframe for reporting
  - Clear up the guidances, these were difficult to implement, based on experience, client scenarios and working group feedback
  - *Provide auto-populated report to registrants with the NDCs for which reporting is necessary – for example the CDER Direct BNCC process
  - *Use the data to better focus existing regulatory programs

*There is a footnote in the guidance indicating that the actual reporting exercise will serve to help identify discrepancies in packaging description that exist between drug listing data and the actual product labeling et. al.

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Thank You

- SPL Process Team
- FDA –
  - CDER NextGen Tech Team
  - FDA\CDER\Office of Pharmaceutical Quality
  - SBIA

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