U.S. FOOD & DRUG ADMINISTRATION

CDER Direct
Electronic Submissions Portal

503B Product Reporting Submission

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Agenda

- **Part I**
  - **What is Product Reporting?**
  - **Regulation**
- **Part II**
  - **LIVE demonstration**
- **Part III**
  - **FAQs**
  - **Related Resources**

Regulation

- **The Drug Quality and Security Act**
  - Created a new section 503B in the FDCA
  - A compounder can become an “outsourcing facility”
- **An “outsourcing facility” is defined as**
  - as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B.

Regulation

- Upon Registration, an outsourcer must:
  - Submit an initial product reporting of all compounded products
  - Product reporting must be submitted in June and December of each year
    - Report products produced during the previous six month
    - For example, June 2017 product reporting should include products produced between December 1, 2016 through May 31, 2017.

Live Demonstration of CDER Direct Product Reporting Submission

http://direct.fda.gov

Helpful Hints

- Labeler-Product Codes
  - Only in 10 digit format
  - A single SPL file can contain multiple products with the same ingredients but different strengths
    - *Each strength is a different product and thus requires a different product NDC*
    - *After creating a product, save it, and return to the main screen to add another product with the same ingredients but different strength formulation*

Helpful Hints

- Source NDC is ***REQUIRED*** for all source drug ingredients
  - Data Files for Unfinished Drugs are available on FDA's National Drug Code (NDC) Directory: https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm
- Prepare ahead of time to get ingredient NDCs
- Dietary Supplements used as active ingredient
  – TBD

FAQs

- **What can be included in one product report SPL?**
  - For a unique drug, one SPL can include:
    - multiple strengths
    - package sizes
    - source NDC numbers
- **What is FDA's standard for NDC numbers?**
  - FDA enforces the standard 10-digit, 3-segmented, hyphenated NDC.
    - xxxxx-xxxx-x (5-4-1)
    - xxxxx-xxx-xx (5-3-2)
    - xxxx-xxxx-xx (4-4-2)
  - A company must use the **same** configuration above for all of its NDCs

FAQs

- **How long does it take to submit a product report SPL?**
  - There is a labor cost for creating the initial product report; however, SPL allows previous files to be saved. Therefore, subsequent reports will require much less time to update and submit. We estimate each initial SPL file can take 1 – 2 hours to create and submit.

- **Why should I save SPL files I've submitted?**
  - FDA recommends saving product report SPL files for future use. This saves the time it takes to recreate all of the product data and provides consistency in product data across reporting periods.

FAQs

- **What is required to be included in a product report?**
  - The National Drug Code (NDC) number of the final product, if assigned.
  - The active ingredient and strength of active ingredient per unit.
  - The NDC number of the source drug or bulk active ingredient, if available.
  - The source of the active ingredient.
  - The dosage form and route of administration.
  - The package description.
  - The number of individual units produced.

FAQs

- **During each reporting period, what timeframe should the report cover?**
  - Drug product reports submitted between June 1 and June 30 of each year must report products produced during the previous six month period (December 1 through May 31).
  - Reports submitted between December 1 and December 31 of each year must report drug products produced during the previous six month period (June 1 through November 30).

FAQs

- **If I did not compound any drugs during the previous 6-month period, do I have to submit a product report?**
  - Yes, submit a single SPL submission stating that no products have been produced. If an individual product was not compounded during a 6 month period while others were, then only submit SPL submissions for the products that were compounded.
- **If I submitted a report upon initial registration before June or December, do I still need to submit a product report for the upcoming reporting period?**
  - Yes, registered outsourcing facilities must submit a report upon initial registration under section 503B of the FD&C Act and twice each year thereafter, once in June and once in December.

FAQs

- **What information from my product report will be published?**
  - For drugs compounded at outsourcing facilities, we plan to publish the following data elements:
    - NDC of the final product (if assigned)
    - name of the outsourcing facility
    - dosage form
    - name of the active ingredient
    - strength of the active ingredient per unit
    - package size
    - package type

Related Resources

- **The Drug Quality and Security Act: Human Drug Compounding Outsourcing Facility:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm

- **Guidance for Industry: Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):** https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377051.pdf

Related Resources

- **Guidance for Industry: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):** http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424303.pdf

- **503B Compounding Dashboard:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm

Questions

- eDRLS Helpdesk: edrls@fda.hhs.gov
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