Drug Amount Reporting: Registration and Listing Regulatory Background

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September 2022

Why Registration and Listing?

CARES Act drug amount reporting requirements pertain to registrants of listed drugs.

Poll Question

How familiar are you with registration and listing requirements?

A. I’m an expert. I submit registration and listing data all the time.

B. I’m somewhat familiar but I’m not an expert.

C. What is registration and listing?

Establishment Registration and Drug Listing

- Drug manufacturers are required to register their establishments and list all drugs they manufacture for U.S. commercial distribution
  - Section 510 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360
  - Codified under 21 CFR Part 207
- Drug listing information is reported to FDA using the National Drug Code (NDC)
  - Drug Listing Act of 1972

Definitions

Manufacturer under 21 CFR 207.1:

- Means a person who owns or operates an establishment that manufactures a drug or an animal feed bearing or containing a new animal drug.
- Includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug, or an animal feed bearing or containing a new animal drug.

Definitions – Continued

- The term "manufacture, preparation, propagation, compounding, or processing," as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers.
- When not modified by "domestic" or "foreign," the term manufacturer includes both domestic manufacturers and foreign manufacturers.

Definitions – Continued

Registrant under 21 CFR 207.1:

- Means any person that owns or operates an establishment that manufactures, repacks, relabels, or salvages a drug, and is not otherwise exempt from establishment registration requirements under section 510 of the Federal Food, Drug, and Cosmetic Act or this part.

Definitions – Continued

Private Label Distributor (PLD) under 21 CFR 207.1:

- Means, with respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed.

Definitions – Continued

Commercial Distribution under 21 CFR 207.1:

- Means any distribution of a human drug, except for investigational use under part 312 of this chapter, and any distribution of an animal drug or an animal feed bearing or containing an animal drug, except for investigational use under part 511 of this chapter. The term does not include internal or interplant transfer between registered establishments under common ownership and control, including a parent, subsidiary, or affiliate company. For foreign establishments that manufacture, repack, relabel, or salvage, or for foreign private label distributors, the term "commercial distribution" has the same meaning except the term does not include distribution of any drug that is neither imported nor offered for import into the United States.

Drug Listing Requirements

- Registrants must list all drugs they manufacture
  - no later than 3 calendar days after the initial registration of the establishment. 21 CFR §207.45
- Listing updates must be submitted in June or December of the same year. 21 CFR §207.57(b)(1)
- If no updates, the listing data must be certified between October 1 and December 31. 21 CFR §207.57(b)(2)
- Required drug listing data included in 21 CFR §207.49.

Drug Listing Requirements

- Required for ALL drugs:
  - Active Pharmaceutical Ingredients (Bulk drug substance)
  - Drugs for further processing
  - Finished dosage forms
  - Human and animal drugs
  - OTC and prescription drugs
  - Biologics
  - Approved and unapproved drugs
  - Drugs for export only

CMO and PLD Listing Requirements

- A PLD that does not engage in the manufacture, repacking, relabeling, or salvaging of a drug is exempt from registering with FDA, *21 CFR 207.17(b).*
- Under § 207.41, the CMO must register its establishment with the FDA and each human drug it manufactures must be listed under two NDCs:
  - one that includes the registrant's own NDC labeler code (regardless of whether the drug is commercially distributed under the registrant's own label)
  - one that includes the NDC labeler code of the PLD

NDC Assignment in Drug Listing

- NDC is the unique identifier assigned to all drugs in U.S. commercial distribution.
- Three segments: labeler code, product code, package code
- Each unique drug product should be assigned a unique product code under the same labeler code.
- Each unique package size and type should be assigned a unique package code under the same labeler code and product code.
- Proposed Rule: Revising the National Drug Code Format and Drug Label Barcode Requirements

NDC Assignment in Drug Listing

- Co-packaged drug products:
  - Can be a combination product, or not.
  - For purpose of drug listing, they are considered a kit.
  - There should be at least one drug part.
  - NDC product code assigned to the overall kit should be different than the NDC product code assigned to each drug part.
  - Non-drug parts should not be assigned any NDCs.
  - If the drug part(s) are individually available for commercial distribution, it/they should also be individually listed.

NDC Assignment in Drug Listing

- Multi-level packaging:
  - Multiple packaging levels of the same drug product (i.e., multiple vials or blister packs in a carton).
  - All packaging levels (with respective NDC and packaging description) should be included in the packaging section of the SPL.
  - Any packaging level not intended for commercial distribution on its own should be included as an inner level.

Resources

- Electronic Drug Registration and Listing System (eDRLS) | FDA
- Electronic Drug Registration and Listing Instructions | FDA
- Electronic Registration and Listing Compliance Program | FDA

Questions

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