CDER Direct Drug Listing 101- The Basics

Drug Listing

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Agenda

• Who must list
• When to list
• How to submit a Drug Listing SPL using CDER Direct
• Summary
• Do’s & Don’ts
• Helpful Resources
“Who”

• Unless exempt, ALL registrants must list all drugs manufactured for commercial distribution

• Contract manufactures (CMO) must list under their own labeler code

• CMO who manufacture for private label distributors (PLD) must also list for PLDs, using the PLD’s labeler code. PLDs may list their own products as an authorized agent.
“When”

• Initial- Listing information must be submitted within 3 days of the initial registration.

• Updates- You can update any changes to the listing every June and December, preferably ASAP.

• Annual listing certification- Accepted updates to the listing certifies your listing for the calendar year and the next calendar year.
How to submit a Drug Listing SPL using CDER Direct

https://direct.fda.gov/
Summary

• Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S and their representative labeling

• Listing data is also used by the public including healthcare providers and other organizations in academia and industry

• Have a standard operation procedure or system in place to verify the accuracy of listing at least twice a year
WE WANT DRUG LISTING INFORMATION TO BE ACCURATE, COMPLETE AND UP TO DATE!
Drug Listing
Do’s

• Registrants must list all drugs they manufacture
• Check listings at a minimum every June and December for accuracy
• Private Label Distributors (PLDs) may list own drug
• Include the complete supply chain under Establishments
• Include Inactive ingredients
Don’ts

• Don’t list Non-Drugs with CDER
• Don’t make assumptions
• Don’t omit data to pass automated validations
• Don’t include multiple email addresses when requesting for assistance
Helpful resources

- Electronic Drug Registration and Listing instructions
- Strength Conversion in Drug Listing
- OTC Active Ingredients
- Electronic Code of Federal Regulations
- edrls@fda.hhs.gov