Top Do's and Don'ts

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Electronic Drug Registration and Listing Using CDER Direct – October 8, 2020

Learning Objectives

- Establish best practices for registration and listing
- Understand pitfalls that lead to deficient submissions

Registration Do's

- Register domestic establishments no later than 5 calendar days after beginning to manufacture a drug. *21 CFR 207.21(a)*
- Register foreign establishments before a drug manufactured at the establishment is imported or offered for import into the U.S. *21 CFR 207.21(b)*
- Renew your registration annually (between October 1 and December 31). *21 CFR 207.29(b)*

Registration Do's – Changes and Updates

- Expedited registration updates must be sent within 30 days of:
  - Closing or selling an establishment
  - Changing an establishment's name or physical address
  - Changing any contact info of the official contact or the United States agent.
    - *An email notification about terminating or designating an employee or agent does not suffice.*

Registration Don’ts

- Do NOT register if you do not perform any drug manufacturing activity
- Do not include vendor’s contact info as the establishment or registrant’s contact info
- Do not register an establishment, unless you are an authorized agent

Labeler Code (LC) Do's

- Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug must apply for an NDC labeler code. *21 CFR 207.33(c)*
- NDC format under a single labeler code must remain the same
  - Example: 5-4-1 or 5-3-2 format
- Labeler Code Request SPL must be updated within 30 days of:
  - Any changes in labeler contact info
  - Any changes to the activities and business operations

Labeler Code (LC) Do's

- LCs can be transferred as part of mergers/acquisitions
  - LCs can be transferred only if *all** drug products are transferred/ acquired
    - *If some products are not transferred, they must be delisted
  - LC Request info must be updated to include the latest information
    - New labeler name, address, business operation, if any
    - New contact info, if any
  - Drug listing info for each drug listing file must be updated to include the new labeler

Labeler Code (LC) Don’ts

- Do not request a LC if you already have one assigned
  - If you run out of available product codes under your assigned LC and NDC format, you can request another LC
- Do not include vendor’s contact info as the LC Request’s contact info

Listing Do's

- Registrants must list all drugs they manufacture
  - no later than 3 calendar days after the initial registration of the establishment. *21 CFR 207.45*
- Private Label Distributors (PLDs) may list own label drug
- Check listings every June or December for accuracy

Listing Do's

- If no updates, listing certification must be submitted between October 1 and December 31
  - Listing certifications for products with open compliance cases will be accepted (if no errors) but certification date won't be extended until the case is closed.
- Subsidiary or parent company can list drugs on behalf of establishments under same ownership
- Include the complete supply chain under "Establishments"

Listing Do's

- Labeling information of a listed repackaged drug must follow the source drug's labeling updates
- Inclusion of inactive ingredients is mandatory
- The application number must be an approved active application and refer to the listed drug

Listing Don’ts

- DO NOT LIST NON-DRUGS WITH CDER
- Don’t use certification lapse to discontinue a drug
- Don’t submit without double checking / proofreading

Challenge Question #1

Changes in labeler code information including the name, physical address, email address, or other contact information must be updated within:

A. 60 days

B. 90 days

C. 30 days

D. Every June and December

Challenge Question #2

Double checking a listing before submitting is important because?

A. Some errors cannot be fixed by a subsequent submission. They must be fixed through manual override.

B. Multiple submissions clog the FDA system and slows the entire process for everyone.

C. Submitting incorrect information will result in a warning letter.

D. FDA charges per submission so multiple submissions cost additional money.

Resources

- Section 510 of the FD&C Act: http://uscode.house.gov/view.xhtml?path=/prelim@title21/chapter9/subchapter5&edition=prelim
- 21 CFR Part 207: https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5
- R&L Compliance webpage: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm531142.htm

Questions?

Compliance questions: edrls@fda.hhs.gov

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