Complying with Labeler Code Request Requirements

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Electronic Drug Registration and Listing (eDRLS) Using CDER Direct - 2024

Learning Objectives

- Provide a list of required data when a labeler code is requested from FDA
- Identify some common labeler code related issues
- Explain why a labeler code may get inactivated immediately

What is a Labeler Code?

- First segment of the National Drug Code (NDC)
- Numeric 4 or 5 characters
  - Under 21 CFR 207.33(b)(1)(i), the length will increase to 6 digits once we run out of 5-digit codes
- Assigned by FDA

Labeler Code Requirements

- Section 510 of FD&C Act 21 U.S.C. 360(b) (c), (d), and (i)
- 21 CFR 207 Subpart C
  - Subpart C, as part of NDC discussion
  - 21 CFR 207.33(c):
    - Required information
    - Update requirements

Who Will be Assigned a LC?

- Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug
  - FDA will make the determination for assignment

What Information is Required?

- 207.33(c)(1):
  - The name, physical address, email address of the person for whom the NDC labeler code is requested
  - The types of activities in which the person requesting the NDC labeler code engages
  - The type(s) of drug(s) to which the NDC labeler code will be applied

Compliance Program

- Started in 2015
- Assures data integrity and focuses on requirements under 21 CFR 207 and section 510 of the FD&C Act in reference to submissions
  - Deficiency letters
  - Additional action

Labeler Code Compliance

- Labeler data is submitted accurately and completely
- Labeler updates are submitted within 30 calendar days after any change
- Labeler codes are assigned by FDA

Common Labeler Code Issues

- Contact information is outdated
- Company goes out of business but does not inactivate its labeler code (after delisting all its drugs)
- The labeler code name is not updated in all drug listing SPLs after it has been updated in the labeler code SPL

Your LC Request Submission is not in Compliance:

- If business operations are not complete or accurate
- If the type(s) of drug(s) (i.e., human, animal, prescription, OTC) is not provided correctly
- The updates are not submitted within 30 days of the change (e.g., business operation, labeler contact information)

After Receiving a Deficiency Letter

- Provide all the required updates within 30 days of receipt of the letter
- If no response is received:
  - The assigned LC may get inactivated
  - An inactivated LC cannot be used for drug listing submissions

Instant Inactivation

- If labeler code was never assigned by FDA
- If labeler code was assigned by FDA based on false information submitted by the labeler
- A notification about inactivation is sent to labeler contact

Challenge Question #1

- Labeler Code Request SPL is only submitted once: when you're requesting a new labeler code.

A. True

B. False

Challenge Question #2

- Which data is required for LC Request submissions to FDA:

A. Labeler email address

B. Labeler business operation(s)

C. Manufacturing establishment(s)

D. Only A and B

Challenge Question #3

- Currently, how many digits is a labeler code?

A. 5

B. 4 or 5

C. 4, 5, or 6

D. None of the above

Closing Thought

Submit accurate and complete information to FDA when you request a labeler code and follow all the update requirements to avoid a compliance case.

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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