Labeler Code Request Highlights

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OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct
2024 SBIA Workshop - September 12, 2024

Learning Objectives

After participating in this session, attendees should be able to:

- Describe timing requirements to update labeler code (LC) information
- Provide steps to reactivate FDA-initiated LC inactivation
- Describe LC update requirements for merger/acquisition cases

Labeler Code Updates

- Within 30 calendar days after any change
- Per 21 Code of Federal Regulations 207.33(c)(2)
- Official communication from FDA

Labeler Code Updates

- FDA sends communications to labeler contacts for:
  - Listing data deficiency
  - Annual reminders
  - New agency initiatives and requirements
  - Data requests, updates or clarifications

Challenge Question #1

Labeler Code Information including the name, physical address, email address and other contact information must be updated within:

A. 90 days

B. 30 days

C. 60 days

D. Every June and December

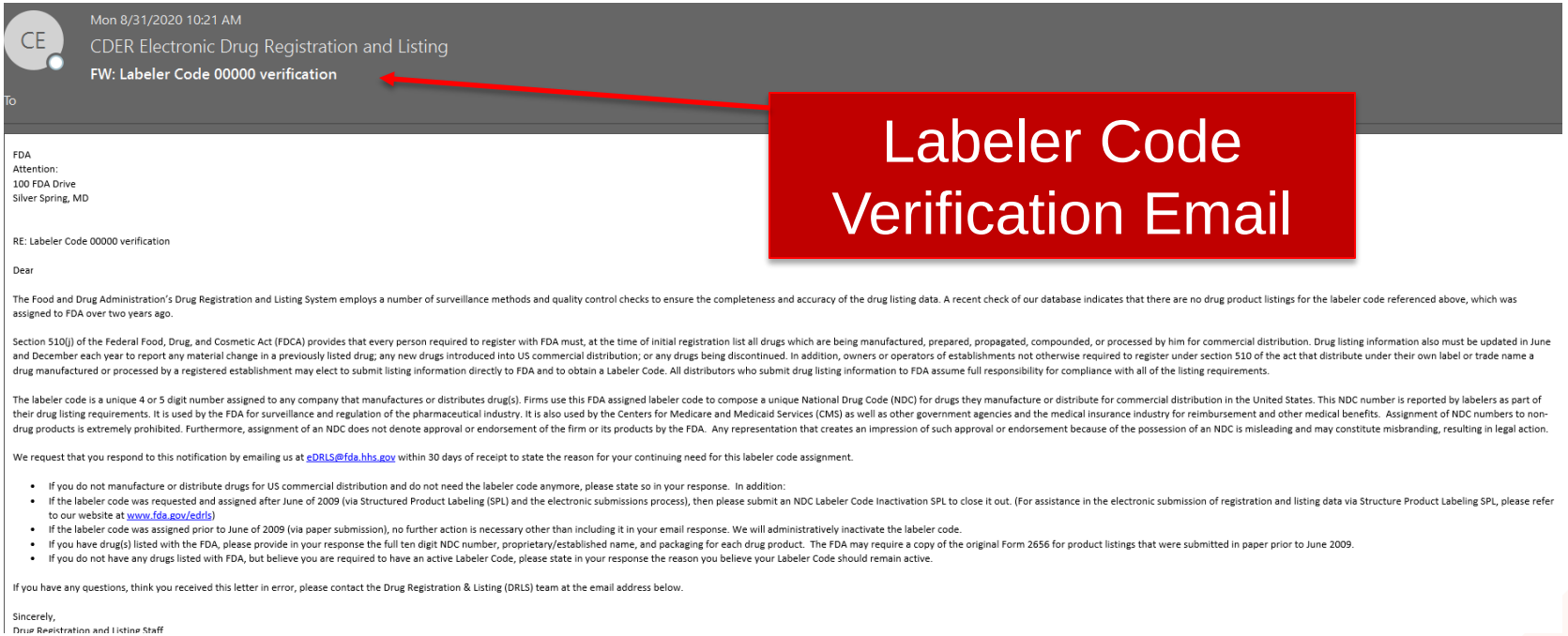
Labeler Code Inactivation

- No drugs listed 24 months = automatic inactivation
- LCs may be inactivated without prior notice:
  - Not assigned by FDA
  - Obtained by providing false information

Labeler Code Verification

- Prior to FDA-Initiated LC Inactivation
  - Email sent to LC's associated contact
  - Notification: inactivation initiated 30 days from email
  - Action required:
    - List product or provide reason for no listing

Labeler Code Verification Email



CE

Mon 8/31/2020 10:21 AM

CDER Electronic Drug Registration and Listing

FW: Labeler Code 00000 verification

To

Labeler Code Verification Email

FDA
Attention:
100 FDA Drive
Silver Spring, MD

RE: Labeler Code 00000 verification

Dear

The Food and Drug Administration's Drug Registration and Listing System employs a number of surveillance methods and quality control checks to ensure the completeness and accuracy of the drug listing data. A recent check of our database indicates that there are no drug product listings for the labeler code referenced above, which was assigned to FDA over two years ago.

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FDCA) provides that every person required to register with FDA must, at the time of initial registration list all drugs which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution. Drug listing information also must be updated in June and December each year to report any material change in a previously listed drug; any new drugs introduced into US commercial distribution; or any drugs being discontinued. In addition, owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the listing requirements.

The labeler code is a unique 4 or 5 digit number assigned to any company that manufactures or distributes drug(s). Firms use this FDA assigned labeler code to compose a unique National Drug Code (NDC) for drugs they manufacture or distribute for commercial distribution in the United States. This NDC number is reported by labelers as part of their drug listing requirements. It is used by the FDA for surveillance and regulation of the pharmaceutical industry. It is also used by the Centers for Medicare and Medicaid Services (CMS) as well as other government agencies and the medical insurance industry for reimbursement and other medical benefits. Assignment of NDC numbers to non-drug products is extremely prohibited. Furthermore, assignment of an NDC does not denote approval or endorsement of the firm or its products by the FDA. Any representation that creates an impression of such approval or endorsement because of the possession of an NDC is misleading and may constitute misbranding, resulting in legal action.

We request that you respond to this notification by emailing us at eDRLS@fda.hhs.gov within 30 days of receipt to state the reason for your continuing need for this labeler code assignment.

- If you do not manufacture or distribute drugs for US commercial distribution and do not need the labeler code anymore, please state so in your response. In addition:
- If the labeler code was requested and assigned after June of 2009 (via Structured Product Labeling (SPL) and the electronic submissions process), then please submit an NDC Labeler Code Inactivation SPL to close it out. (For assistance in the electronic submission of registration and listing data via Structure Product Labeling SPL, please refer to our website at www.fda.gov/edrls)
- If the labeler code was assigned prior to June of 2009 (via paper submission), no further action is necessary other than including it in your email response. We will administratively inactivate the labeler code.
- If you have drug(s) listed with the FDA, please provide in your response the full ten digit NDC number, proprietary/established name, and packaging for each drug product. The FDA may require a copy of the original Form 2656 for product listings that were submitted in paper prior to June 2009.
- If you do not have any drugs listed with FDA, but believe you are required to have an active Labeler Code, please state in your response the reason you believe your Labeler Code should remain active.

If you have any questions, think you received this letter in error, please contact the Drug Registration & Listing (DRLS) team at the email address below.

Sincerely,
Drug Registration and Listing Staff

Verification Email Response

- If you receive inactivation notification:
  - Respond within 30 days
  - Reply to eDRLS@fda.hhs.gov
  - State reason for continued need for LC
  - State reason LC no longer required

Labeler Code Inactivation Notification

FDA
Attention
FDA Drive

Silver Spring, MD

RE: Labeler Code 00000 inactivation notification

Dear

This is an FDA automatically generated email to notify you that Labeler Code 00000 assigned previously by FDA is now inactivated.

Labeler codes that have no products listed for two years are sent notification 30 days prior to inactivation. If there is no response to the notification then your labeler code is inactivated. This Labeler Code cannot be used for NDC assignment to drugs or drug listing with FDA. If you have a drug or drugs that you are about to enter in US commercial distribution, please provide us with details for each drug in an email. We request information on product name, active ingredient(s), strength, labeling, start marketing date and intended NDC for each drug in order for us to determine if the labeler code should be reactivated. For more information visit: www.fda.gov/edrls

If you think you received this letter in error, please contact the Drug Registration & Listing (DRLS) team at the email address below.

Sincerely,
Drug Registration and Listing Staff
FDA/CDER/Office of Compliance
edrls@fda.hhs.gov

Challenge Question #2

What happens if a labeler code does not have any products listed for two years?

A. It will be automatically reactivated by the FDA

B. It will be permanently inactivated by the FDA

C. It will receive a notification 30 days prior to inactivation

D. It will be transferred to a different regulatory agency

Mergers & Acquisitions

- Company specific business decisions
  - Every case is unique
- Companies can merge or be acquired
- Products can be acquired with or without a merger

Mergers & Acquisitions

- Transfer or keep all parts of products
- LCs can be acquired
- Can require updates to:
  - Registration SPL, Labeler Code SPL, and Listing SPL

Mergers Example 1

- Company A and B merge into Company C
- Company C acquires entire drug catalogue for Company A & B
- Company C keeps Company A's Labeler Code

Mergers Example 1

- Company C:
  - Update Company A's LC and Registration SPLs
  - Update Company A listing with new labeler name (Company C)
  - Delist all Company B's drugs under Company B's LC
    - Relist under new Company C's LC and labeler name
  - Inactivate Company B's LC
  - If Companies A, B and C are registered with FDA, update the registration SPLs accordingly

Acquisitions Example 1

- Company A acquires human prescription line from Company B
- Company B continues manufacturing human OTC drugs
  - LC cannot be transferred
  - Acquired drugs must be delisted under Company B's LC
  - Acquired drugs must be listed under Company A's LC

Challenge Question #3

Mergers and acquisitions can require updates to:

A. Registration SPL

B. Labeler Code SPL

C. Listing SPL

D. Any of the above

Resources

- https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions
- https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes

Summary

- 30 calendar days to make updates
- LC without listed drugs inactivated after 24 months
- Companies transfer LCs and all/part of products
- Follow all necessary post-merger steps

Questions?

Division of Labeling, Registration and Unapproved Drugs, OUDLC
CDER | US FDA

eDRLS@fda.hhs.gov

Closing Thought

With the resources for labeler codes and mergers & acquisition cases, you can more confidently provide updates.


FDA
U.S. FOOD & DRUG
ADMINISTRATION