

# Labeler Code Request Highlights

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OC | CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct

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# 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



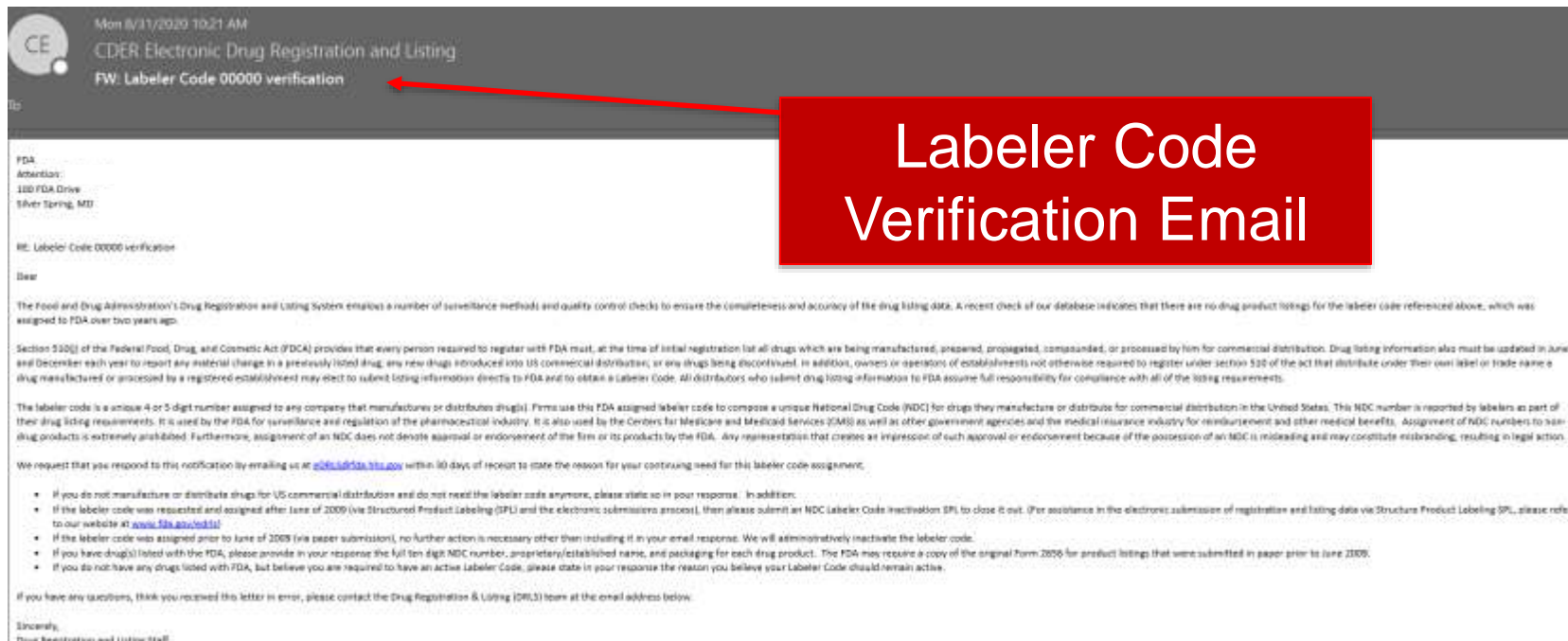
- No drugs listed 24 months = automatic inactivation
- LCs may be inactivated without prior notice:
  - Not assigned by FDA
  - Obtained by providing false information

# 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



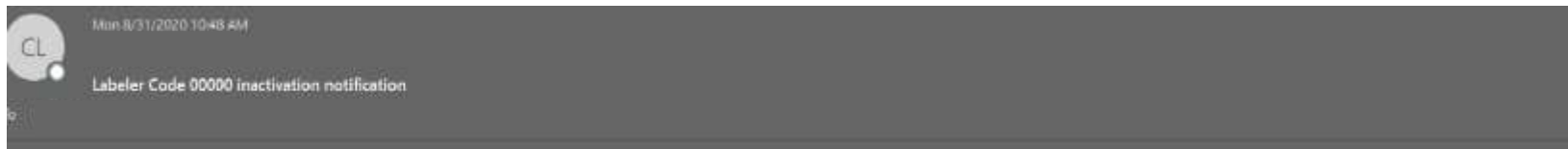


# Verification Email Response



- If you receive inactivation notification:
  - Respond within 30 days
  - Reply to [eDRLS@fda.hhs.gov](mailto: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/cderls](http://www.fda.gov/cderls)

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  
[cdrls@fda.hhs.gov](mailto:cdrls@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?

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# Closing Thought



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

