

Updates, Mergers, and Acquisitions

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Learning Objectives

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

- Describe timing requirements to update labeler code information
- Describe labeler code update requirements in merger and 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

Mergers & Acquisitions



- Company specific decisions
- Companies can merge or be acquired
- Products can be acquired with or without a merger
- LCs can be acquired
- Can require updates to:
 - Registration SPL, Labeler Code SPL, and Listing SPL

Mergers (Example)

- Company A and B merge into Company C
- Company C keeps Company A's Labeler Code
 - Company A or C:
 - Update Company A's LC and Registration SPLs
 - Update drug listing with new labeler name

Mergers (Example)

- Company A and B merge into Company C
- Company C keeps Company A's Labeler Code
 - Company B or C:
 - Discontinue drug listings associated to Company B's LC
 - Relist all drugs under Company C's LC and NDC
 - Inactivate Company B's LC and deregister its registration

Acquisitions (Example)

- Company A acquires company B
 - Company B should deregister
 - Company B's LC should be updated or inactivated
 - If Company B's products are also acquired

Acquisitions (Example)

- Company A acquires human prescription line for 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



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

- a) Within 60 days
- b) Within 90 days
- c) Within 30 days
- d) Every June and December

Questions?

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