Data Inactivation

Vikas Arora, PharmD.
Consumer Safety Officer
US Food & Drug Administration
CDER
OC/OUDLC/DRLB

Learning Objectives

- Discuss Drug Listing Requirements
- Describe Annual Certification Requirements
- Discuss Drug Inactivation FRN
- Describe the Data Inactivation Timelines
- Discuss Inactivation
  - January
  - July
- Describe Inactivation Due to Compliance Case

Drug Listing Requirements

- **Section 510(b) of the FD&C Act** requires that drug establishments register, and renew their registration annually during the Oct-Dec renewal period
- **Section 510(j)of the FD&C Act** requires that registrants provide a list of all drugs manufactured for commercial distribution at the time of registration
- **Section 510(j)(2)(D) of the FD&C Act** requires that registrants send in any material changes to any listing already on file every June or December

Annual Certification Requirement

- 21 CFR 207.57 (b)(2)
  - After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single “no changes” certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.
- If drug listing was updated during current calendar year, you are certified.

Data Inactivation FR Notice

- Federal Register Notice published on August 14, 2019
  - Federal Register :: Drugs Intended for Human Use That Are Improperly Listed Due to Lack of Annual Certification or Identification of a Manufacturing Establishment Not Duly Registered With the Food and Drug Administration; Action Dates
- First inactivation began in September 2019 shortly after the FR Notice

Data Inactivation FR Notice

- Thirty days after publication of this notice, and every January thereafter, FDA will begin to inactivate human drug listings that remain uncertified from the previous renewal period of October 1 to December 31. In addition, every July thereafter, FDA will begin to inactivate human drug listings that remain active and certified after the June listing update, but still contain at least one establishment that is not currently registered in accordance with FDA's requirements.

Data Inactivation Timelines

- Two annual inactivation periods for different violations:
  - January
  - July
- Intent is to keep the data as accurate and up to date as possible
- Notification e-mail is sent to the labeler points of contact with the estimated date of inactivation if no updates are made
  - Verify that the Labeler Code SPL has the most updated contact information

January Inactivation

- Due to missing October-December annual certification period for drug listings not updated during calendar year with a new version of an updated SPL in accordance with 21 CFR 207.57 (b)(2)
- If you receive an inactivation notification e-mail, a new version of the drug listing SPL must be submitted, with any pertinent updates, in order to reactivate/correct the data depending on the situation

January Inactivation Notification Action

- If drug is still in commercial distribution:
  - Blanket No Change Certification cannot be completed after the annual certification period has ended
  - Must submit a new version of SPL for each drug listing
- If drug is no longer in commercial distribution:
  - Inactivation due to lack of certification is not exempt from listing update responsibilities
  - Must submit an updated SPL indicating a completed marketing status and marketing end date

July Inactivation

- Drug listing files that remain active and certified after the June listing update, but contain at least one establishment not duly registered with FDA
- 21 CFR 207.57 (b) states “Registrants must review and update their drug listing information each June and December.”
  - FDA allows companies with active drug listings until the June update deadline to get the establishment registered or identify a new one.
  - If the update not made by the June requirement, in July, we inactivate those drug listings which are still linked to an unregistered establishment.

July Inactivation Notification Action

- If drug in distribution but manufactured at a different facility:
  - Provide a new version of the drug listing SPL identifying the new manufacturing establishment and removing the ones no longer utilized
- If drug in distribution but manufacturer failed to renew registration:
  - Submit an updated establishment registration for the existing establishment or contact the establishment and notify them of the need to renew its registration with FDA

July Inactivation Notification Action

- If drug is no longer being manufactured for distribution:
  - Inactivation is not exempt from listing update responsibilities
  - Must submit an updated SPL with completed marketing status and marketing end date

Inactivation due to Compliance Case

- Compliance Cases can be created at any time of year due to incorrect:
  - Labeler code
  - Establishment registration
  - Drug listing data
- Unresolved compliance cases can lead to data inactivation

Consequences of Inactivation

- Removal from FDA publications
- Flagged in DailyMed
- CMS Reimbursements issues
  - Listing inactivation dates are transmitted through the NDC SPL Data Elements (NSDE) File

Resolving Inactivation

- Once inactivation has occurred, new SPL submission is required
- Can take 24-48 hours for a successful submission to be reactivated
- If inactivation is due to a compliance case, new SPL will need manual evaluation and can require additional time
  - Data will not be reactivated unless the case is closed
- Can take another 24 hours for reactivated data to be re-published in databases

Challenge Question #1

Material changes to any drug listing on file are required every:

A. January and February

B. October and December

C. January and July

D. June and December

Challenge Question #2

Drug listing data inactivation occurs every:

A. January and February

B. October and December

C. January and July

D. June and December

Summary

- Review your drug listing often for any changes/updates
- Make sure Labeler code contact information is correct
- Data inactivation does not fulfill obligation to delist
- If inactivation notification is received, please take necessary action to avoid inactivation
- If inactivated, updated SPL must be submitted in order to reactivate

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

edrls@fda.hhs.gov