FDA's Drug Listing Inactivation Project

Leyla Rahjou-Esfandiary, Pharm. D.
Lead CSO
DRLS/ Office of Compliance
CDER/ US FDA
Electronic Registration and Listing Using CDER Direct
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Learning Objectives

- Provide FDA's listing inactivation periods
- Describe the reasons drug listing files get inactivated by FDA
- Describe how drug listing data can be reactivated

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

2016 Revision

- 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.

Listing Data Inactivation Project

- Federal Register Notice published on August 14, 2019: https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-17436.pdf
- Two annual inactivation periods:
  - January
  - July

January Inactivation

- Human drug listing files that remain uncertified from the previous renewal period of October 1 to December 31
- First inactivation: January 2020
- Will occur annually
- Email notification sent prior to inactivation

January Inactivation

- Drug still in the market
- Missed certification period

Reactivate the data by submitting a new version of the drug listing SPL. "No Change Certification SPL" not accepted after December 31.

January Inactivation

- Drug is no longer in commercial distribution

Access the listing SPL, change the marketing status to "complete" and add an end marketing date which is the last lot expiration date. Inactivation due to lack of certification does not eliminate listing update responsibilities.

July Inactivation

- Human drug listing files that remain active and certified after the June listing update, but still contain at least one establishment not duly registered with FDA
- First inactivation: July 2020
- Will occur annually
- Email notification sent prior to inactivation

July Inactivation

- Drug still in the market, manufactured at a different facility
- Missed June listing update requirement

Submit an updated drug listing file for that NDC identifying a new manufacturing establishment that is currently registered

July Inactivation

- Drug still in the market
- Manufacturing establishment failed to renew its 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

- Drug no longer manufactured

Access the listing SPL, change the marketing status to "complete" and add an end marketing date which is the last lot expiration date. Inactivation due to outdated establishment informatin does not eliminate listing update responsibilities.

Compliance Inactivation

- Applicable to compliance cases
- Can be labeler code, registration or listing data
- Can happen any time during the year
- Reactivation through updated SPL requires closure of the compliance case

To Date…

FDA has inactivated outdated listing data for 53,196 products through its listing data inactivation project

Listing Data Publication

- Inactivated records are removed from:
  - NDC Directory search (data moves to “Excluded Packages and Products” file)
  - DailyMed
- FDA listing inactivation and reactivation dates are transmitted to:
  - NSDE File (used by CMS for reimbursement)

Listing Data re-Publication

- Once the data is reactivated
- Can take 24-48 hours after a successful submission for the data to be reactivated
- Can take another 24 business hours for the reactivated data to be re-published

Challenge Question #1

- If a listing data is inactivated due to a compliance case, an FDA compliance officer must review the updates, in order for the data to be reactivated.

  A. True

  B. False

Challenge Question #2

- FDA's drug listing inactivation project periods are:

  A. June and December

  B. October – December

  C. January and July

  D. It can happen anytime of the year

Biggest Takeaway

- REVIEW AND UPDATE YOUR DRUG LISTING FILES!
- Keep your contact information current

Questions?

Leyla Rahjou-Esfandiary, Pharm. D.
Lead CSO
DRLS/ Office of Compliance
CDER/ US FDA
Leyla.Rahjou-Esfandiary@fda.hhs.gov
eDRLS@fda.hhs.gov


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