

Data Removals and Flags

Tasneem Hussain Pharm. D.

Consumer Safety Officer (CSO) – Drug Registration and Listing Branch

**Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration**

CDER Direct Workshop September 28, 2023



Learning Objectives

- Identify the types of data removal actions
- Identify several online publications where data can be removed from
- Identify the flags associated with data removal in different online publications

Registration Data Removal



- Establishment registration data is removed
 - By firms:
 - Deregistration, out of business or dropped
 - By FDA:
 - Failure to renew registration-> expired
 - Failure to respond to and correct errors included in deficiency letters
 - Inactivation



Listing Data Removal

- By Firms:
 - Delisting (once the revision reaches the marketing end date)
- By FDA:
 - Failure to respond and correct errors identified in deficiency letters
 - Inactivation
 - Failure to update or certify product as active (January inactivation)
 - Inclusion of an expired establishment in a drug listing submission (July inactivation)

Data Removal from Online Publications



- Establishment registration data
 - Removal from Drug Establishment Current Registration Site (DECRS)
- Drug listing data
 - Removal from National Drug Code (NDC) Directory
 - DailyMed – Listing data removed due to egregious errors
 - NSDE File - NDC SPL Data Elements File
 - Includes inactivation or reactivation dates



Registration Removal Flags

- Drug Establishment Current Registration Site (DECERS) flags:
 - E –(Erroneous data is excluded) – Establishment registration data is excluded from DECERS
 - I –(Inactivated) Establishment registration data is removed from DECERS

Listing Removal Flags



- NDC Directory flags:
 - **E** - This product's listing data has been removed from the NDC Directory for failure to respond to FDA's requests for correction to deficient or non-compliant data
 - **U** - the listing data is expired due to lack of certification
 - **I** – the data removed from the NDC Directory but is included in the "Excluded" file and it refers to a listing data that is inactivated

DailyMed Flag

- |- the listing data was inactivated by FDA

NIH U.S. NATIONAL LIBRARY OF MEDICINE REPORT ADVERSE EVENTS | RECALLS

DAILYMED ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS | MORE WAYS TO SEARCH

Enter drug, NDC code, drug class, or Set ID

HOME + NEWS FDA RESOURCES + NLM SPL RESOURCES + APPLICATION DEVELOPMENT SUPPORT HELP

LABEL: [REDACTED]

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

Contains inactivated NDC Code(s)

NDC Code(s): [REDACTED]

Packager: [REDACTED]

Category: HUMAN PRESCRIPTION DRUG LABEL

DEA Schedule: None

Marketing Status: unapproved drug other



Challenge Question #1

- Which of the following can be a reason for listing data removal
 - A. Inclusion of a current establishment registration in a drug listing
 - B. Failure to submit a drug listing within 2 years
 - C. Failure to respond to a listing deficiency letter
 - D. None of these are reasons for listing data removal



Challenge Question 2

- Where does the “E” flag appear?
 - A. NDC Directory
 - B. DailyMed
 - C. DECORS
 - D. Answers A and C are both correct

Summary

- Registration and listing data can be removed from online publications
 - Failure to comply with registration and listing regulations
 - Failure to respond and correct errors identified in deficiency letters
 - Failure to renew a registration for an establishment
 - Failure to certify the listed products as active
- The flags available on NDC Directory and DECRS alert viewers of status of data

Questions?

Tasneem Hussain Pharm. D.

Consumer Safety Officer – Drug Registration and Listing Branch

Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

edrl@fda.hhs.gov