

# Data Removals and Flags

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# 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 (DECRS) flags:
  - E –(Erroneous data is excluded) – Establishment registration data is excluded from DECRS
  - I –(Inactivated) Establishment registration data is removed from DECRS


# 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




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**Contains inactivated NDC Code(s)**

**NDC Code(s):** 

**Packager:** 

**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. DECERS
  - 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?

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