Downstream Effects

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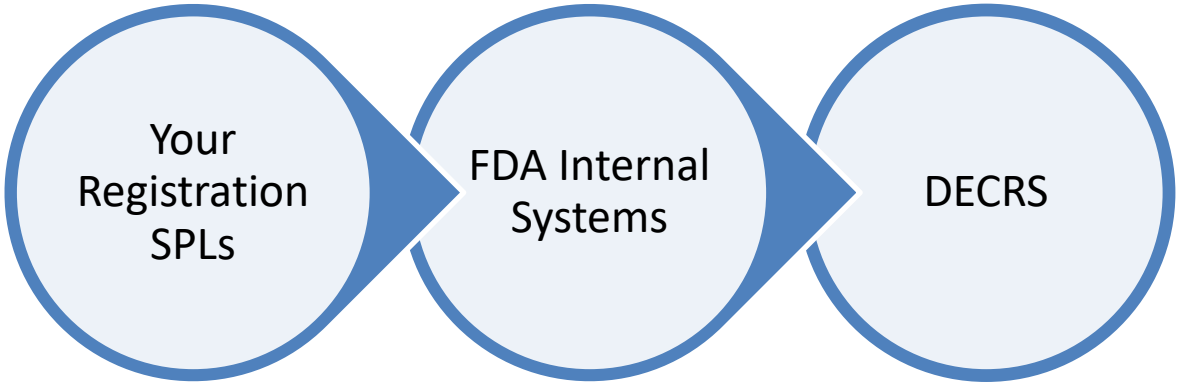
CDER Direct Workshop – September 28, 2023

Learning Objectives

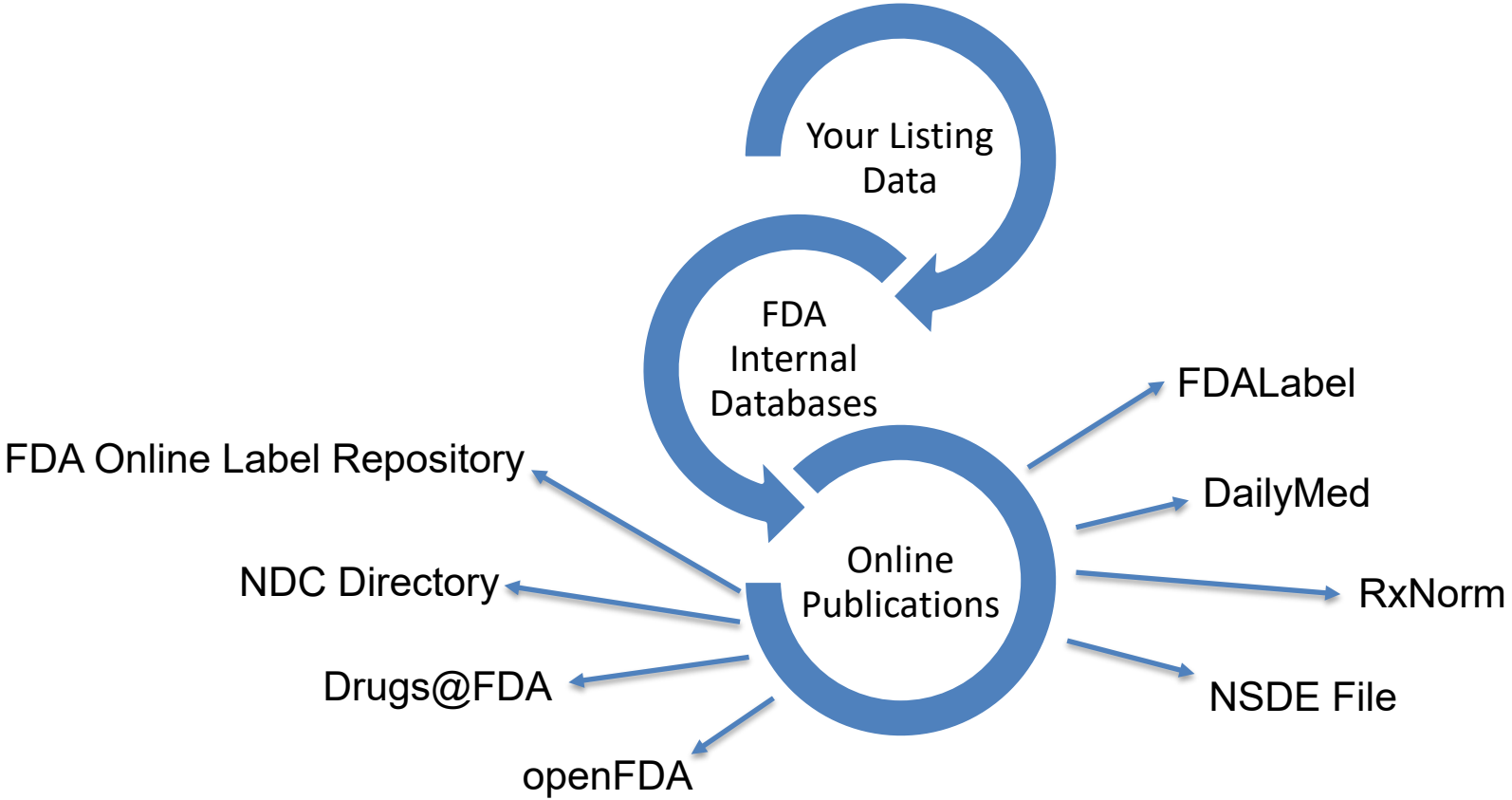
- Identify online publications
- Describe ways to report data discrepancies to FDA
- List potential real-life examples caused by data deficiency

Registration Data

- Published on Drug Establishments Current Registration Site | FDA



Listing Data



Who Uses the Data

Inside FDA

- Facility inspection planning
- Statutory facility fee assessments
- Drug shortage initiatives
- Drug amount reporting
- Safety assessments

Outside FDA

- Other government agencies
- Pharmaceutical industry
- Drug databanks
- Academia and research
- Healthcare providers and patients

Why Data Integrity is Important

- Reliability of CDER's site selection model and product catalog

Location	CY 2017	CY 2018	CY 2019	CY 2020	CY 2021	CY 2022
Domestic	3,479	3,297	3,139	879	1,311	2,061
Foreign	1,457	1,321	1,200	204	57	381
Total	4,936	4,618	4,339	1,083	1,368	2,442

CGMP Inspections of Registered Domestic and Foreign Drug and Device Establishments

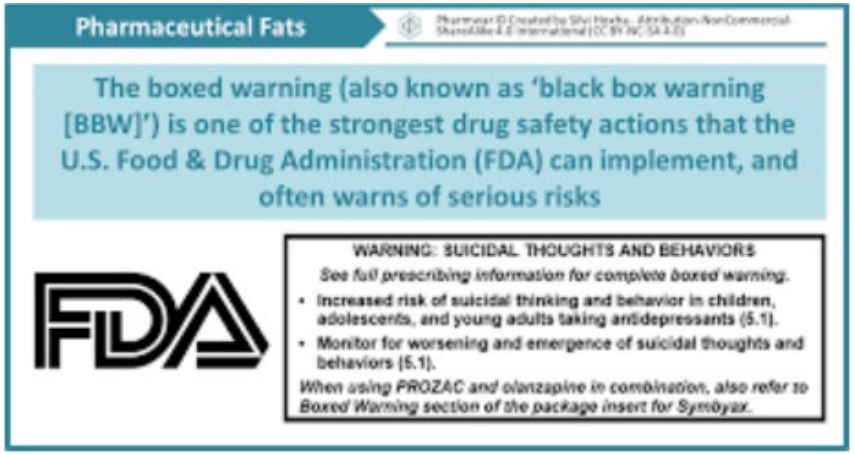
Source: Annual Report on Inspections of Establishments CY 2022

Why Data Integrity is Important

- Inaccurate listing or NDC assignment can lead to medication error
  - A drug is co-packaged with two injectable vials
  - Drug A and Drug B have the same NDC
  - Patient was injected with the same drug twice

Why Data Integrity is Important

- Healthcare providers might miss key labeling information
  - A repackager drug listing was not updated with a boxed warning after the source drug's labeling update



Why Data Integrity is Important

- Incorrect packaging information can lead to reimbursement or reporting mistakes

Comprehensive NDC SPL Data Elements File (NSDE)

NSDE | FDA

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CDER NextGen

Important Safety Initiatives

- We play a key role in preventing incidents related to substandard, falsified, and harmful drugs:
  - Diethylene glycol/ethylene glycol contamination WHO urges action to protect children from contaminated medicines
  - FDA ophthalmic drugs initiative FDA Issues Warning Letters to Firms Marketing Unapproved Eye Products | FDA

Poll Question

It is in the best interest of the pharmaceutical company, as well as public health, to submit correct registration and listing data to FDA.

A. True

B. False

Find Data Discrepancy in FDA Online Publications?

- Contact FDA:
  - Drug Registration and Listing Branch: eDRLS@fda.hhs.gov
  - Division of Drug Information: DrugInfo@fda.hhs.gov

Challenge Question #1

Which one of these publications is managed by FDA?

A. Comprehensive NDC SPL Data Elements File

B. Drug Establishment Current Registration Site

C. Neither

D. Both

Challenge Question #2

Which of the following statements is NOT true?

A. Anyone can contact FDA about data discrepancy found in its published registration and listing data.

B. FDA can make corrections to its online published registration and listing data.

C. FDA's listing data is used by other government agencies for coding, reimbursement, prescribing, and dispensing of drugs.

D. NDC assignment is not part of drug approval but is an important safety aspect of a drug.

U.S. FOOD & DRUG ADMINISTRATION

Questions?

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