How are FARs/BPDRs utilized within Site Selection Model (SSM)

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An Update on Field Alert Reports (FAR) and Biological Product Deviation Reports (BPDR) – May 24, 2023

Learning Objectives

- Identify the section in the Federal Food, Drug, and Cosmetic Act (FD&C Act) where a risk-based schedule is codified
- List the factors used in the CDER Risk-Based Site Selection Model
- Explain how FAR and BPDR are used in the CDER Risk-Based Site Selection Model

CDER's Risk-Based Site Selection Model (SSM)

Purpose

To prioritize manufacturing sites for routine quality-related (current good manufacturing practice (CGMP)) surveillance inspections.

Background

Rank drug manufacturing sites for CGMP surveillance inspections ***based on risks to public health***.

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

CDER's Risk-Based Site Selection Model (SSM) and CDER's Site Surveillance Inspection List

- The SSM considers risks to drug quality as may arise from violations of CGMP requirements.
- The SSM uses risk factors to generate CDER's Site Surveillance Inspection List (SSIL).
- The SSIL prioritizes sites for routine surveillance inspections

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

Risk Factors Stated in Section 510(H)(4) of the FD&C Act

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.

(G) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

Risk Factors Used in the SSM

SSM generates a risk based score for each site.

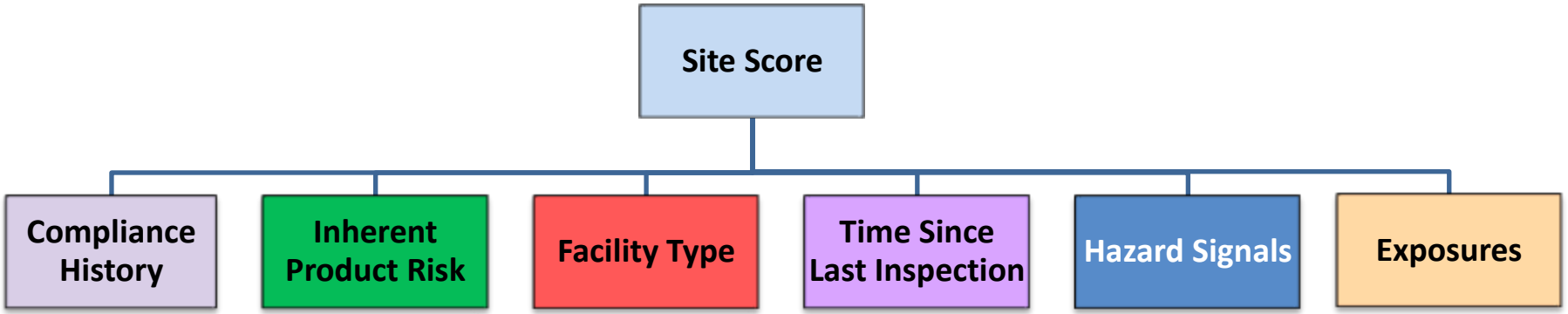
This site score is based on empirical evidence collected by FDA, subject matter experts' judgment, or a combination of both.

The following are currently identified as risk factors in the SSM:

- Site type
- Time since last surveillance inspection (or if the site was never previously inspected)
- FDA compliance history
- Compliance history of country or region
- Foreign regulatory authority inspectional history (with an authority deemed capable under section 809 of the FD&C Act)
- Patient exposure
- Hazard signals: FAR, BPDR, Recalls and others
- Inherent product risk

More information regarding the CDER's Risk-Based Site Selection Model can be found in Manual of Policies & Procedures (MAPP) 5014.1

Risk Factors Used in the SSM



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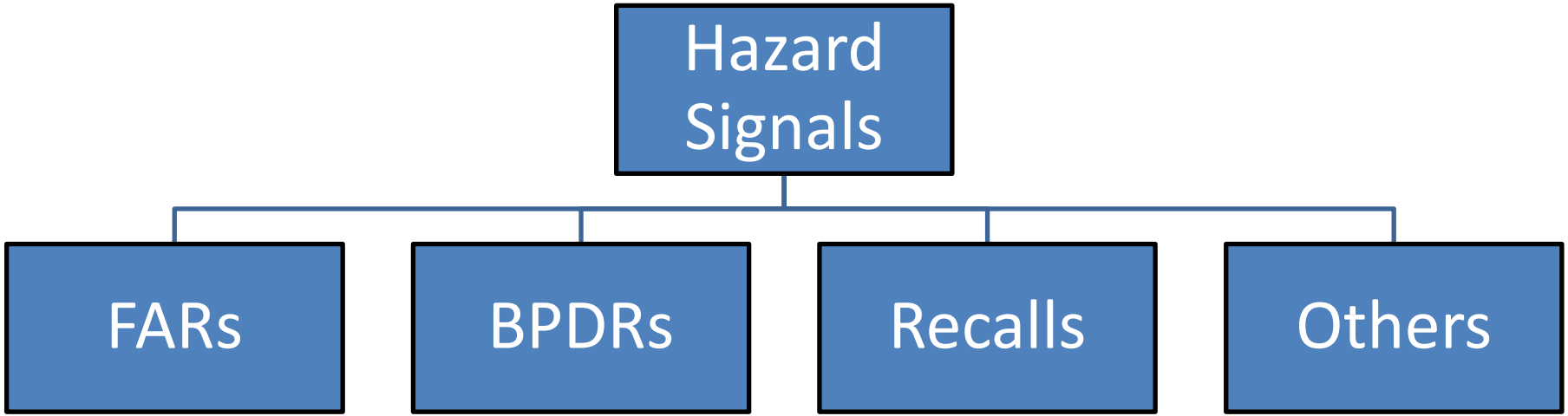
Hazard Signals Used in the SSM



Summary

- CDER Risk-Based Site Selection Model use risk factors consistent with section 510 of the FD&C Act
- SSM calculate a score for each facility using risk-based factors. Factors in the SSM includes, compliance history; inherent product risk; facility type; time since last inspection; hazard signals; and exposure.
- FAR and BPDR are some of the hazard signals contributing to the model.

Challenge Question #1

CDER Risk-Based Site Selection Model uses risk factors consistent with which Section of FD&C Act?

A. 704

B. 809

C. 510

Challenge Question #2

What type of signals are FAR and BPDR in the CDER Risk-Based Site Selection Model?

A. Traffic Signals

B. Hazard Signals

C. Analog Signals

U.S. FOOD & DRUG ADMINISTRATION

Thank You

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