Office of Inspections and Investigations / OII

FDA INSPECTIONS

WHO DOES FDA INSPECT?

FDA inspects and assesses domestic and foreign regulated firms to determine their compliance with applicable laws and regulations, such as the Food, Drug, and Cosmetic Act (FD&C Act) and related Acts.

TYPES OF INSPECTIONS

- **Surveillance**
- **Follow-up**
- **For-cause**
- **Application-based**

WHAT DOES FDA INSPECT?

FDA inspects human and animal foods, human and animal drugs, medical devices, biological and tobacco products, cosmetics, and radiation-emitting electronic devices.

WHAT IS FDA'S INSPECTION PROCESS?

Firms that manufacture, process, pack, or hold FDA-regulated **products are subject to FDA's regulatory authority.**

A FDA investigator inspects a firm to **enforce regulations** and **verify regulatory compliance.**

Following the inspection, the FDA investigator **initially classifies** the firm's **compliance level as NAI, VAI, or OAI.** Final classification is determined by the appropiate FDA Center or Compliance unit.

WHAT DO INSPECTION CLASSIFICATIONS MEAN?

No Action Indicated (NAI) means there were no objectionable observations found. However, "discussion items," which could result in future observations if not corrected, may be shared with the firm.

Voluntary Action Indicated (VAI) means that the investigator discussed objectionable observations at the end of the inspection. Based on the nature of observations and the firm's commitments to voluntarily correct deficiencies, an **official action indicated** classification is not warranted. Usually, the facility is issued a Form FDA 483 at the conclusion of the inspection.

Official Action Indicated (OAI) means a firm is not in compliance and must make preventative or corrective actions. A Form FDA 483 is issued at the inspection's conclusion.

Inspections represent a **"snapshot in time"** and do not result in permanent classifications. FDA does not endorse firms as approved or unapproved.

Learn more about inspections here: https://bit.ly/FDAInspectionsProcess

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