Preventing Regulatory Actions

FDA Small Business
Regulatory Education for Industry (REdI)
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Poll

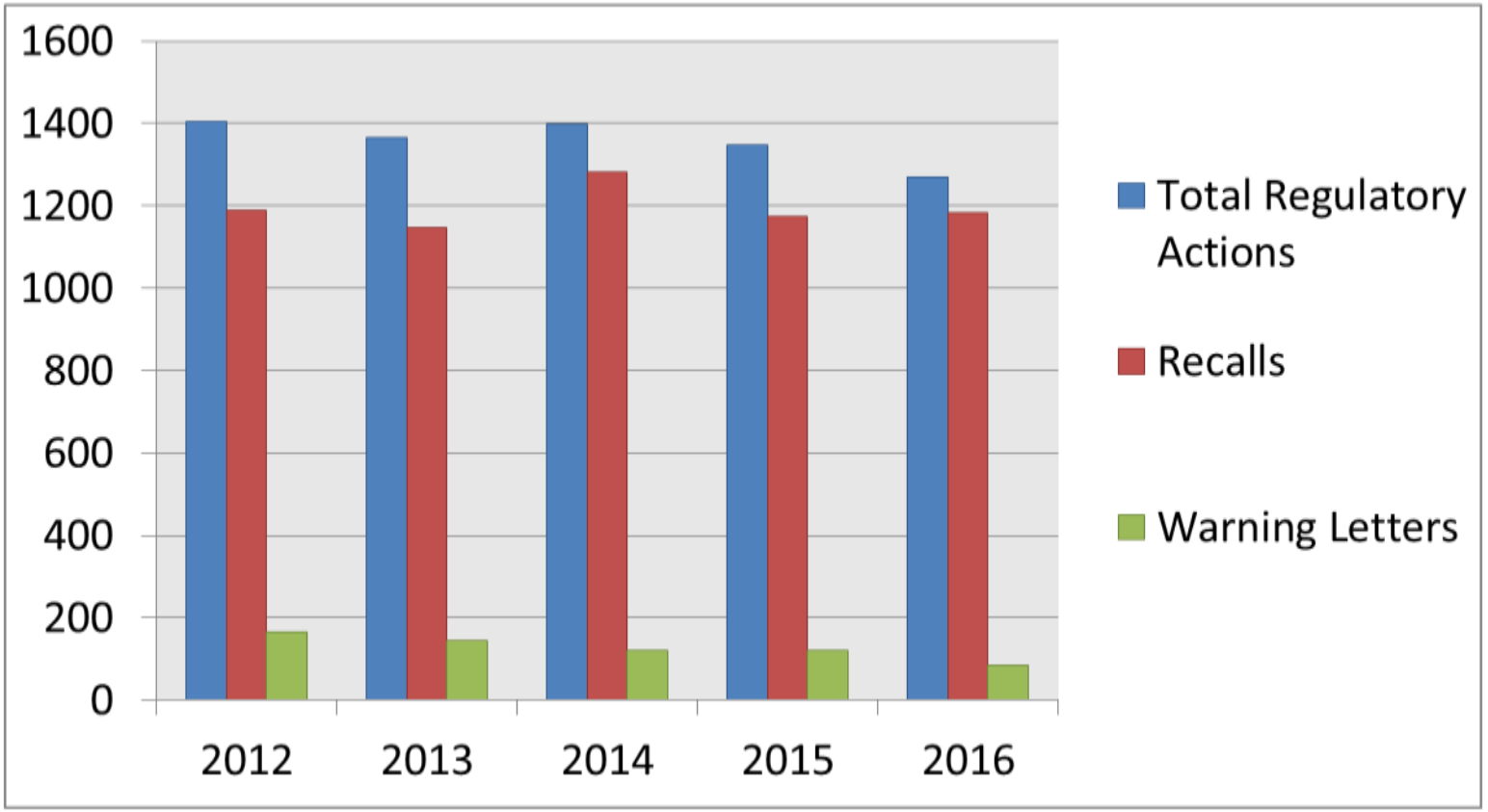
Do you know of a firm that has been subjected to any type of FDA regulatory action, for example, a Warning Letter, Seizure, Injunction, Civil Money Penalty?

1) Yes

2) No

3) I am not sure

CDRH Regulatory Actions



- CDRH conducted 1,269 regulatory actions during Fiscal Year 2016.
- 6% decrease in regulatory actions from previous Fiscal Year.

Learning Objectives

- Provide FDA's regulatory authority
- Review the types and purposes of FDA regulatory actions
- Discuss prevention of FDA regulatory action

FDA Authority

- Federal Food, Drug, and Cosmetic Act

  (Sections 302 – 304, 501, 502, 518, 801, etc.)

- Title 21 Code of Federal Regulations (21 CFR)

  (Part 7, 11, 800-1299, etc.)

Types of Regulatory Actions

- Regulatory Meeting
- Untitled Letter
- Warning Letter
- Warning Letter with Detention without Physical Examination
- Warning Letter without Detention

Types of Regulatory Actions continued

- Product Recall
- Seizures
- Injunctions
- Civil Money Penalties
- Criminal prosecution

Regulatory Meeting

Informs Manufacturer of violations/clarifies violations

Advisory/Administrative Letters

Letter	Firm type	Issued	Written response required	Notify other federal agencies
Untitled Letter	D/F	Within 6 months	No	No
Warning Letter (WL)	Domestic	Within 4 months	Yes	Yes
WL with Detention without Physical Examination	Foreign	Within 4 months	Yes	Yes (Import Alert)
WL without Detention	Foreign	Within 4 months	Yes	Yes

D: Domestic Firm
F: Foreign Firm

Product Recall

- Prompt correction or removal of violative device for:
  - Repair
  - Modification
  - Relabeling
  - Inspection
  - Adjustment
- Reduces risk to health
- Can be voluntary or mandatory
- Classified as Class I, II, or III

Example: Product Recall

- Herpes Simplex Virus (HSV) 1 & 2 Direct and Group A Streptococcus (GAS) Test
  - Poor lamination
  - Leakage into adjacent wells
  - Yield false positives, false negative, or invalid test results
  - Improper patient treatment
  - May cause serious adverse health consequences
- Customer Correction Notice letter sent
- Customer instructed to only run full discs
- Discard discs even after partial run

Example: Seizure

- Obstetrical and gynecological surgical devices seized
  - Labeled as sterile or ethylene oxide processed
  - Sterilization not complete
  - 40,000 units affected
- FDA issued Safety Alert
- Accompanied U.S. Marshal service during seizure

Example: Injunction

- Firm that manufactured electrical devices was enjoined
  - Failure to correct significant violations of the QS regulation
- FDA initially issued Warning Letters in 1998 and 1999
- Ordered shutdown of facility immediately
- Entered into Consent Decree of Permanent Injunction
  - Required to hire an expert
  - Expert report firm's status of compliance to FDA
  - Firm must pay for FDA inspections
- Conduct recall

Civil Money Penalties

- Knowingly aware of violations
- Risk to public health

Criminal Prosecution

- Individuals can be prosecuted
- Investigations are conducted by special investigators
- FDA works with the United States Department of Justice

Most Frequent Regulatory Actions

- Product Recalls
- Warning Letters

Most Frequent Violations Cited to Support Regulatory Action

1. Processes not validated
2. Purchasing controls not implemented
3. CAPA subsystem not implemented

1. Validate Required Processes

- Identify and validate all processes requiring validation
- Ensure predefined acceptance criteria are met and documented
- Calibrate equipment used
- Ensure all required reviews and approvals are documented and dated

2. Implement Purchasing Controls

- Ensure purchasing controls in place are adequate for all products/processes
- Define specifications that are clear and understood
- Document evaluation of suppliers
- Obtain agreement, where possible, to address changes to product or services

3. Implement Effective CAPA Subsystem

- Document all CAPA SOPs
- Ensure staff are trained on all applicable CAPA procedures
- Ensure actions implemented are documented and completed according to CAPA SOP
- Ensure CAPAs are verified/validated before closure

3. Implement Effective CAPA Subsystem (2)

- Ensure management is aware of the performance of the CAPA subsystem
- Continue to manage/improve the CAPA subsystem
- Identify linkages to other elements of the Quality System with CAPA subsystem

3. Implement Effective CAPA Subsystem (3)

- Establish and maintain complaint files
- Document and address all complaints received according to complaint SOP
- Ensure procedures for handling complaints are linked to other elements in the CAPA subsystem
- Use proper tools for performing investigations

General Tips for Preventing FDA Regulatory Actions

- Review and understand the regulatory requirements
- Establish and maintain Standard Operating Procedures (SOPs) for all required activities
- Ensure employees are adequately trained on and follow all applicable procedures
- Document all activities completed
- Ensure management is aware of the effectiveness of the quality system

Summary

- FDA regulatory actions correct violations and remove violative devices from the market.
- FDA can criminally prosecute responsible individuals who fail to address product and patient safety problems.
- Understanding your own operations and the regulatory requirements will contribute to preventing regulatory actions.
- Respond to regulatory action in a timely manner.

Questions

Please complete the session survey:

surveymonkey.com/r/DEV-D2S07

Call to Action

- Understand and comply with all applicable FDA laws and regulatory requirements.

- Always respond to FDA regulatory actions within the appropriate time frame.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