Preventing Regulatory Actions

FDA Small Business
Regulatory Education for Industry (REdI)
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Tonya Wilbon
Postmarket and Consumer Branch Chief
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Poll

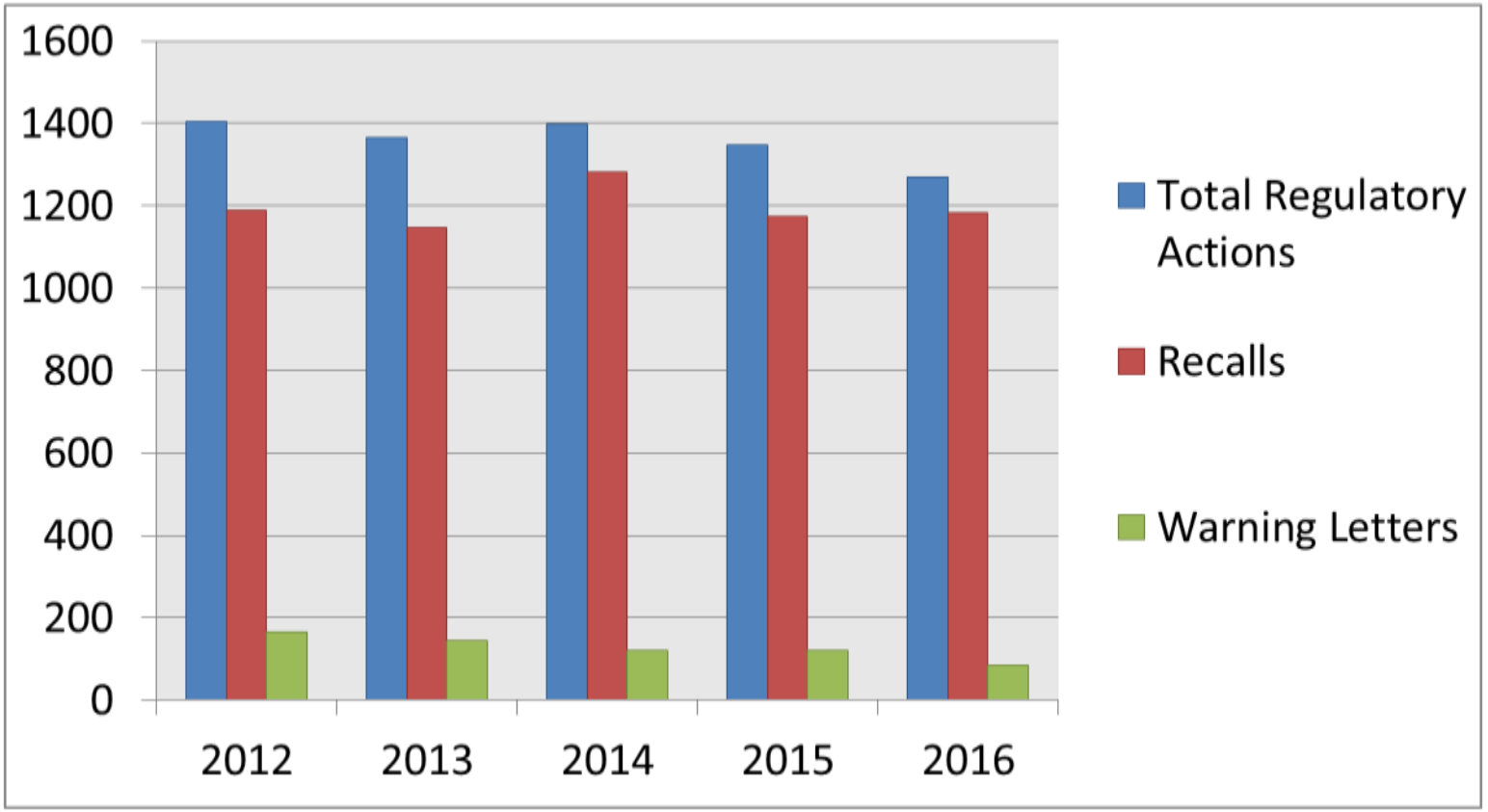
Are you aware of a firm that was subjected to an FDA regulatory action?

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

- Prompts correction/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
- Most common type of regulatory action

Example: Product Recall

- Herpes Simplex Virus (HSV) 1 & 2 Direct IVD 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
- Firm sent “Customer Correction Notice letter” to customers
- Customers were instructed to:
  - run full discs only
  - discard discs even after partial run

Seizure

- Method used by FDA to take quick control of violative product
- FDA files a “Complaint for Forfeiture” with the courts
- FDA takes possession of violative devices

Example: Seizure

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

Injunction

- History of continuous significant violative practices
- Civil process to stop or prevent violation of the law
- Use of current evidence of violation of the law
- FDA files a “Complaint for Injunction” with the courts

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

- Applies to individuals and not firms
- Investigations are conducted by special investigators
- FDA works with the United States Department of Justice

Most Frequent Violations Cited to Support Regulatory Action

I. Processes not validated
II. Purchasing controls not implemented
III. CAPA subsystem not implemented

I. Validate Required Processes

- Identify and validate all processes as required
- Meet and document all predefined acceptance criteria
- Calibrate equipment used
- Document and date all required reviews and approvals

II. Implement Purchasing Controls

- Ensure purchasing controls 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

III. Implement Effective CAPA Subsystem

- Document all CAPA SOPs
- Train staff on all applicable CAPA procedures
- Document and complete actions implemented according to CAPA SOPs
- Verify/validate CAPAs before closure
- Ensure management is aware of how the subsystem is performing

III. Implement Effective CAPA Subsystem (cont)

- Continue to manage/improve the CAPA subsystem
- Identify linkages to other Quality System elements
- Establish and maintain complaint files
- Document and address all complaints per SOP
- Use proper tools for performing investigations

General Tips for Preventing FDA Regulatory Actions

- Review and understand regulatory requirements
- Establish and maintain SOPs for all required activities
- Train employees on all applicable procedures
- Document all completed activities
- Ensure management is aware of how effective the quality system is performing

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 regulatory requirements helps prevent 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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