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Warning Letters and Untitled Letters

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Definitions

- **Warning Letters**
  - Correspondence to regulated industry about violations FDA has documented
  - Notification to responsible person that FDA considers a product, practice, process, or other activity to be in violation of the FD&C Act or FDA regulations
  - Issued only for violations of regulatory significance, i.e., violations that may lead to enforcement action if not adequately corrected

Definitions

- **Untitled Letters**
  - Initial correspondence with regulated industry that cites violations that do not meet threshold for a Warning Letter
  - For circumstances where FDA needs to communicate with industry, but may not be prepared to take enforcement action

History

- **Background**
  - Prior to 1991, FDA issued Notices of Advanced Findings and Regulatory Letters
  - In 1991, FDA began issuing Warning Letters and Untitled Letters
  - In 2001, procedures were changed so that all Warning Letters had to be reviewed and cleared by FDA's Office of the Chief Counsel
  - In 2009, OCC review was limited to letters that present significant legal issues

Importance

- **Importance of Warning Letters to FDA**
  - Half of Commissioner Hamburg's Six Steps to Increased Enforcement
    - Speed up the Warning Letter process – Decentralize issuance of Warning Letters by limiting OCC review
    - Prioritize follow-up on Warning Letters – Quickly assess and follow-up on corrective actions taken by firms in response to a Warning Letter
    - Implement Warning Letter close-out process – If firms take corrective action, issue a Close-Out Letter and post it on the FDA website

Format

- **Common Elements**
  - Title: "WARNING LETTER"
  - Addressed to highest known official in the firm
    - If Warning Letter concerns inspectional findings, a copy is sent to highest known official at facility
  - Dates of inspection; a description of violative product, practice, or process; and citation to law or regulation violated
  - Demand that corrective action be taken, and that a written response be provided within 15 days

Format

- **Additional Common Elements**
  - Warning that failure to correct the violations may result in enforcement action
  - Statement about the implications for the awarding of federal contracts
  - Instructions on the firm's response, including:
    - Listing each step taken to completely correct the violations and prevent future violations
    - The time for completion of the corrective actions
    - Documentation showing that corrections have been made

Prior Notice

- **Prior Notice**
  - In general, FDA's policy is to provide a warning prior to taking enforcement action, but FDA has no legal obligation to do so
  - FDA will take immediate enforcement action if
    - Violations reflects a history of repeated or continued violative conduct
    - Violations are intentional or flagrant
    - Violations present a reasonable possibility of injury or death
    - Adequate notice has been given by other means, and violations have not been corrected

Significance

- **Significance of Receiving a Warning Letter**
  - Warning Letters are issued only for violations of regulatory significance
    - Significant violations are violations that may lead to enforcement action if not adequately corrected
    - Which violations are significant?
  - Warning Letters are FDA's principal means of achieving prompt, voluntary compliance
  - Warning Letters are posted to FDA's website

Significance

- **Significance of Receiving an Untitled Letter**
  - Untitled Letters cite violations that do not meet the threshold of regulatory significance of a Warning Letter
    - The letter is not titled
    - The letter does not include a warning that failure to take corrective action may result in enforcement action
    - The letter requests (rather than requires) a written response within a reasonable amount of time

Avoidance

- **How to Avoid Receiving a Warning Letter**
  - Adopt a compliance program modeled on HHS's *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*
  - Implement standard operating procedures
  - Conduct training on the compliance program's policies and procedures, as well as SOPs
  - Establish a committee to review and approve all promotional materials
  - Respond promptly and thoroughly to any inspectional observations

Recovery

- **How to Recover After Receiving a Warning Letter**
  - Obtain advice from competent FDA regulatory counsel
  - Request a meeting with appropriate FDA personnel
  - Take corrective action promptly
  - Submit a thorough response to the Warning Letter and, when appropriate, ask that the response be posted on FDA's website

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Close-Out Letters

- **Close-Out Process**
  - FDA will issue a Close-Out Letter if
    - The firm's response to the Warning Letter provided sufficient information to show that the violations have been adequately corrected
    - A follow-up inspection confirms that corrective actions were adequate (or, based on other information, FDA determines that a follow-up inspection is not necessary)
    - The follow-up inspection (or other information) does not reveal other significant violations
  - Close-Out Letters are posted to FDA's website

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Thank you!