Warning Letters and Untitled Letters

Kyle Sampson
Hunton & Williams LLP
• **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
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
• **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 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
• **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
• 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
  – 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 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 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
• 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
Thank you!