Risky Business: New Compliance Challenges for FDA-Regulated Industry

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Risky Business: New Enforcement Challenges

“Every company with products or activities under FDA’s jurisdiction has a duty to comply with the law … to meet the standards that the FDA has set to protect the public.”

FDA Commissioner Margaret A. Hamburg
August 6, 2009
Risky Business: New Enforcement Challenges

» What has changed?
   – Increased enforcement

» Why does it matter?
   – Distribution of products, government contracts, certificates of export at risk, increased risk of product liability/shareholder litigation

» What should you do?
FDA’s Enforcement Initiative

» Post-Inspection Deadlines: Fifteen Working Days
» Accelerated Issuance of Warning Letters
» Closer coordination with other agencies
» Prioritized Enforcement Follow-up
» Immediate Enforcement Action if required
» Warning Letter Close Out Process
Increase in FDA Resources

Over 700 investigators hired and/or on the way

» FY 2011 Budget Request $4.03 Billion
  – 23 percent increase over FY 2010 budget
» FY 2011 -- 718 additional full-time equivalent (FTE) staff to expand programs that protect America’s food supply.
  – More than 425 new FTE in field operations
  – 132 FTE will be new food investigators
» FY 2011 – 215 new FTE for medical product programs (medical devices, human and animal drugs, and vaccines, blood and other biologics.
  – 85 new FTE in FDA field operations, of which 40 will be new investigators
  – The 40 FTE will annually conduct more than 600 foreign and domestic risk-based inspections.
## Increasing Number of Warning Letters

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<td><strong>TOTAL</strong></td>
<td><strong>438</strong></td>
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FDA Administrative and Enforcement Options

» 483s
» Untitled Correspondence
» Regulatory Meetings
» Warning Letters
» Seizures
» Import Detentions
» Injunctions
» CMPs
» Prosecutions (Strict Liability Misdemeanors, Felonies)
Have a Plan

“FDA’s renewed emphasis on enforcement has been recognized – and I am pleased that we’ve been able to see a rise in industry compliance programs … which are the key to preventing problems from occurring in the first place.”

FDA Commissioner Margaret A. Hamburg
April 21, 2010
Does Your Program Include FDA?

» Other Types of Compliance Programs
  – SEC Disclosure Requirements
  – Healthcare (fraud and abuse)
  – Foreign Corrupt Practices Act
  – Government Contracts
  – Antitrust
  – Privacy
  – Intellectual Property
  – EPA
Compliance Program Elements*

» Policies, Procedures and Controls
» Senior level Oversight
» Training/Education
» Communication
» Enforcement
» Auditing and Monitoring
» Response and Correction

* Based on HHS OIG Guidance documents.
The Roadmap

» Structure of the Program

• Written compliance policies and procedures
• Code of Business Ethics and FDA Compliance Program Policy Statement
• Employee certification of compliance with FDA Compliance Program
The Roadmap

» Compliance Objectives
  – What are the company’s top compliance priorities?
  – What are high risk areas for the company?
  – What does the company need to do to achieve and sustain substantial compliance?
  – Will the company devote adequate resources to the compliance program?
The Roadmap

Structure of the Program

• Compliance Officer (CO) and Senior Level Compliance Committee (CC)
• CO should have sufficient knowledge and understanding of the FDCA, regulations and guidance documents
• CO should have a reporting relationship with the CEO and Board of Directors
• CC should advise the CO and provide oversight/management of the program
• Periodic reports to Board
The Roadmap - Training

» Overview of FDA laws and regulations
» Training on doing business in FDA-regulated industry
» Overview of compliance program and obligation of employees to participate in the program
» Job specific training
» Management should support compliance training
» Management should receive same compliance training as other staff
» Board should receive training as well
The Roadmap - Communication

» Consistent regulatory compliance messages
  – Employee roles and responsibilities
  – Importance of following procedures
  – Consequences of non-compliance

» Anonymous employee hotline
  – Promotion of hotline
  – Non-retaliation policy
The Roadmap - Enforcement Policy

» Written enforcement and discipline policy should be available to all employees
» Company should apply enforcement and discipline policies consistently and routinely
» Compliance should be rewarded, as appropriate (non-monetary recognition)
The Roadmap - Auditing and Monitoring

- Internal and external audits
- Qualitative analysis of audit findings, complaints, FDA correspondence (including untitled letters), 483s and Warning Letters
- Track all FDA commitments
- Monitor FDA areas of concern throughout industry
The Roadmap - Response and Correction

» Appropriate reporting to FDA and other legal authorities
» Temporary suspension of operations if necessary
» Removal or demotion of managers who fail to address compliance issues in a timely manner
» Shifting resources to implement corrective action
High Risk Areas

» Release of Unsuitable Product
– Prohibited Act under FDCA
– Possible Risk of Injury to Consumers/Patients
– Increased likelihood of enforcement action
– Risk of product liability litigation
– Adverse publicity associated with recalls, FDA enforcement, lawsuits
High Risk Areas

» Promotion of Products
  – Off-label promotion
  – Unapproved Products/Significant Changes to Claims
FDA Initiatives

» Targeting Promotion of Products on the Internet
  – Internet Week of Action (IIWA)
    • Weeklong effort in November 2009
    • 136 websites targeted
      – Sales of products such as "Herbal Viagra," "Viagra (Brand)," "Xanax (Brand)," and "Valium (Brand)."
    • FDA issued 22 warning letters to operators of websites
    • FDA notified internet service providers and domain name registrants that the websites were selling products in violation of US law.
FDA Initiatives

» Promotion of Products relating to H1N1
  – Unauthorized H1N1 claims prompted first-ever joint warning letter by FDA and FTC regarding supplements purportedly able to stop the spread of H1N1 influenza
  – From May 1 - October 15, 2009, FDA warned more than 75 websites to stop selling more than 135 products with fraudulent H1N1 claims
  – FDA implemented H1N1 Flu Fraud Widget

High Risk Areas

- Supplier Quality
  - Initial Supplier Selection
  - Contracts
  - Risk Management Stratification
  - Risk Based Audit Program
  - Current Supplier Data
  - Corrective Action Planning
Consistent Evaluation of Adverse Events

» Effective complaint handling system
» Proper and timely reporting and monitoring
» Effective Investigations
» Changes to product/labeling based on new information
The Value of Compliance

» Good for business
  – Compliance costs less than enforcement actions

» Personal liability for non-compliance
  – Strict liability for misdemeanors under Park Doctrine
  – Liability for failure to detect and correct violations, or failing to take steps to prevent violations from occurring
Effectiveness of Plan

- Corporate culture will ensure the plan’s effectiveness or its demise
  - Senior management must support the plan
  - Senior management must be held accountable
- Governing body should be sufficiently engaged
- Not a “check the box” exercise
- A “boilerplate” plan will not be effective
- Indicator of Plan’s Success:
  - How much has the company spent on compliance?
  - How much has the company spent on marketing?
Questions?

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Thank you!

Reminder: The slides and a link to a recording of the webinar will be distributed to attendees after the event.