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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

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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?

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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

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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.

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Increasing Number of Warning Letters

	2008	2009	2010
January	49	36	38
February	20	27	73
March	31	33	39
April	34	24	40
May	55	83	
June	46	49	
July	26	42	
August	40	45	
September	47	41	
October	42	72	
November	26	85	
December	22	40	
TOTAL	438	577	

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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)

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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

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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

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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.

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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

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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?

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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

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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

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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

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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)

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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

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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

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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

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High Risk Areas

- Promotion of Products
  - Off-label promotion
  - Unapproved Products/Significant Changes to Claims

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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.

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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

Source: FDA News Release, "FDA, FTC Issue Joint Warning Letter to Web Site Offering Fraudulent H1N1 Flu Supplements", October 19, 2009

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High Risk Areas

- Supplier Quality
  - Initial Supplier Selection
  - Contracts
  - Risk Management Stratification
  - Risk Based Audit Program
  - Current Supplier Data
  - Corrective Action Planning

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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

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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 take steps to prevent violations from occurring

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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?

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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.

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