CFSAN Update

AFDO Annual Educational Conference

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White House Announcements March 14, 2009

- Appointments of Dr. Margaret Hamburg as Commissioner of the Food and Drug Administration, and Dr. Joshua Sharfstein as the Principal Deputy Commissioner
- Creation of a new Food Safety Working Group

"The Food Safety Working Group will bring together cabinet secretaries and senior officials to advise me on how we can upgrade our food safety laws for the 21st century; foster coordination throughout government; and ensure that we are not just designing laws that will keep the American people safe, but enforcing them."

President Obama,
3/14/09 Radio Address

Food Safety Working Group

Co-Chairs: Secretary, Health and Human Services
Secretary, United States Department of Agriculture

- Secretary, Department of Commerce
- Secretary, Department of State
- Director, White House Domestic Policy Council
- Director, Office of Management and Budget
- Director, Office of Science and Technology Policy
- Director, Homeland Security Council
- Director, Council on Environmental Quality
- United States Trade Representative
- Administrator of the Environmental Protection Agency

FDA, CDC and FSIS are active participants in the Working Group, too

Food Safety Working Group Listening Session

- Opportunity to engage stakeholders in a conversation to help shape the principles guiding reform
- 5 breakout groups:
  -- focus on prevention
  -- strengthen surveillance and risk analysis
  -- expand risk-based inspection and enforcement
  -- rapidly respond to outbreaks and facilitate recovery
  -- target resources effectively

FY2010 President's Budget

- The President's FY2010 budget states that it:

  "Invests over $1 billion for Food and Drug Administration food safety efforts to increase and improve inspections, domestic surveillance, laboratory capacity and domestic response to prevent and control foodborne illness."

- FY2009 Foods program funding is about $650M so this would represent another significant increase.

FY 2010 Budget Request
Protecting America's Food Supply

- Develop a system of preventive controls to prevent foodborne outbreaks
- Create an integrated program with states on inspection and enforcement
- Conduct more domestic and foreign inspections
- Conduct more FDA import review and analysis
- Perform greater surveillance for food contamination
- Conduct additional lab analysis of food samples
- Strengthen information technology to support food safety and security

Food Safety Enhancement Act

- Section 105 – Increased inspections
- Section 106 – Access to records
- Section 107 – Product tracing
- Section 108 – Fees for reinspection and recall
- Section 111 – Mandatory recall
- Section 132 – Administrative detention

Food Safety Enhancement Act

- Section 112 – Exchange of Information
- Section 122 – Public Education Program on Food Safety
- Section 133 – Quarantine Authority
- Section 143 – Country of Origin Labeling

FDA Transparency Task Force

"Our administration is committed to making government open and transparent. The Transparency Task Force will give the American people a seat at the table and make the FDA more open and accountable."

HHS Secretary Kathleen Sebelius, 6/2/09

FDA Transparency Task Force

- Seek public input on issues related to transparency
- Recommend ways that the agency can better explain its operations compatible with the appropriate protection of confidential information
- Identify information the FDA should provide about specific agency operations and activities, including enforcement actions and product approvals
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public
- Identify appropriate tools and new technologies for informing the public
- Recommend changes to the FDA's current operations, including internal policies and guidance, to improve the agency's ability to provide information to the public in a timely and effective manner
- Recommend legislative or regulatory changes, if appropriate, to improve the FDA's ability to provide information to the public

FDA Transparency Task Force

- Public meeting June 24

  NTSB Conference Center

  Washington, D.C,

  (see 74 FR 26712; 6/3/09)
- The Task Force will Submit a written report to the Commissioner on their findings and recommendations

FDA External Meetings with Stakeholders

- Dr. Hamburg is scheduling a series of 17 meetings with Stakeholders
- The first meeting occurred last Friday with Cosmetic Industry Stakeholders

External Stakeholder Meetings (Tentative Schedule)

Cosmetic Industry	**June 06**	Drug Industry	June 26
Clinicians (Drug)	June 08	Clinicians (Device)	June 29
Pharmacy	June 10	Patients (#3)	June 30
Patients (#1)	June 12	Consumers (Device)	July 01
Food Industry	**June 15**	Pediatrics	July 06
Patients (#2)	June 17	Consumers (Drug)	July 08
Consumers (Food)	**June 19**	**Public Health**	**July 10**
Women's Health	June 22	Generic Drugs	TBD
Device Industry	June 23		

Reportable Food Registry

- Establish a Reportable Food Registry to which instances of reportable food may be submitted via an electronic portal by responsible parties and regulatory agencies

Reportable food means – an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, will cause serious adverse health consequences or death to humans or animals

Reportable Food Registry

Responsible Parties Include:

- Anyone that submits the registration under section 415(a) (owner, operator or agent in charge of domestic or foreign facility if engaged in manufacturing, processing, packing or holding of food for consumption in the U.S.) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held

Reportable Food Registry

Voluntary Submissions May Also Be Made By:

- Federal, State, and Local Public Health Officials

Reportable Food Registry

FDA Resonsibilities:

- Promptly review and assess information submitted
- Issue or cause to be issued an alert or notification with respect to a reportable food as deemed necessary
- (When necessary) require responsible party to report back to FDA, investigate cause of adulteration, and/or provide notification to sources and recipients of the article of food

Reportable Food Registry

FDA responsibilities – continued:

- Share information and coordinate efforts with Federal, State and local public health agencies
- Share information and coordinate efforts with the Department of Agriculture
- Notify the Department of Homeland Security immediately, if HHS Secretary believes food is intentionally adulterated

Reportable Food Registry

Next Steps:

- FDA will conduct workshops at several locations nationwide to orient constituents
- FDA will publish a final guidance prior to implementation of the portal
- FDA expects the portal to become operational on September 8, 2009
- In the interim, FDA strongly encourages persons to continue to report instances of adulterated food through existing mechanisms, such as notifying the relevant FDA District office