2016 Association of Food and Drug Officials (AFDO) Annual Conference

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U.S. Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN)
Update

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CFSAN 2016 Priorities

FDA Food Safety Modernization Act (FSMA)

Phase 1: Standard Setting

Regulation	Proposal	Final Rule
Preventive Controls (Human Food)*	Jan 16, 2013	Sept 17, 2015
Preventive Controls (Animal Food)*	Oct 29, 2013	Sept 17, 2015
Produce Safety*	Jan 16, 2013	Nov 27, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Nov 27, 2015
Third Party Accreditation	Jul 29, 2013	Nov 27, 2015
Sanitary Transport	Feb 5, 2014	April 6, 2016
Intentional Adulteration	Dec 24, 2013	May 26, 2016

FSMA Implementation

- Publish final rule on Intentional Adulteration
- Education, outreach, and technical assistance on the FSMA final rules
  - For industry
  - For FDA employees
  - For state and tribal partners

Tools for Food Safety

- FSMA gives us new tools to protect public health;
- How to best use our tools to deliver immediate public safety impact?
- As warranted, seek voluntary action;
- As needed, utilize appropriate tools to protect health:
  - Issue public alerts and other press;
  - FDA enforcement tools (ADO, mandatory recall, suspend registration, seizure, injunction, etc.);
  - State action (suspend permit or embargo).

Compliance Program Activities

- ***Product sampling***
  - Micro surveillance field assignments:
    - ✓ FY 2014 – 16: avocados, raw milk, cheese aged sixty days, and sprouts;
    - ✓ FY 2016: cucumbers, and hot peppers
- ***Environmental sampling***
  - Environmental sampling at facilities in varied industry segments (i.e., nut butters, caramel apples, sprouts, other)
- ***FY 2016 activities***
  - Further and increased environmental pathogen verification

Foodborne Pathogens

- Review comments from the Food Advisory Committee on *Listeria monocytogenes* in ready-to-eat foods and update compliance programs, as needed.
- Finalize a report on the pilot sampling program of raw milk cheese aged for a minimum of 60 days, sprouts, and avocados to determine microbial levels, including the presence of pathogens.
- Engage with stakeholders on compliance policies for raw milk cheese to ensure that raw milk cheese continues to be made safely.

Generally Recognized as Safe (GRAS)

- GRAS Final Rule – intend to finalize by end of August 2016

- Two draft guidance documents to follow-
  - What it means to be GRAS
  - GRAS Panels/Conflicts of Interest

Chemical Contaminants

- Updating the 2002 Risk Analysis Framework document.
- Updating, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (also known as the "The Redbook").
- Working with EPA to respond to public comments regarding joint 2014 draft consumption advice concerning methylmercury in fish.

Chemical Contaminants 2016: Inorganic Arsenic (iAs) in Food

- Present in water, soil, and air from natural sources and as a result of human activities;
- For that reason, it is present in certain foods, notably, rice;
- It is a known carcinogen;
- It has been associated with a variety of non-cancer effects (acute and chronic).

FDA's Comprehensive Approach

Risk Management: Infant Cereal Action Level

- FDA proposed to set an infant rice cereal action level of 100 ppb inorganic arsenic.
- In setting action levels, we consider public health risk and may also consider feasibility.
- Reducing iAs levels with an action level will reduce exposure.

Nutrition

- Publish final menu labeling guidance.
- Publish final rule on gluten-free labeling of fermented and hydrolyzed foods.
- Publish final rules updating the Nutrition Facts Label and Serving Size requirements.
- Review comments on the use of the term "natural" in the labeling of human food products and determine next steps.

Nutrition (cont.)

- Release findings of Health and Diet Survey;
- Continue efforts to promote broad, gradual reduction of added sodium in the food supply.
  - Emphasis is on releasing draft voluntary targets to begin a dialogue with industry

Nutrition: Post-NFL

- After FDA publishes final rules updating the Nutrition Facts and Supplement Facts Labels and Serving Size, plan to update other regulations, as needed:
  - Nutrient content claims (e.g., changes due to changes in serving sizes and any changes in daily reference values)
- Healthy: Citizens Petition to update.

Medical Foods

- FDA is working to finalize the Guidance for Industry "Frequently Asked Questions About Medical Foods; Second Edition."
- The guidance is intended to update prior responses and provide responses to additional questions regarding the definition and labeling of medical foods.

Food Safety, Nutrition and Health

Dietary Guidelines and Food Safety

- Many of the foods we encourage Americans to consume for the prevention of chronic diseases are high-risk foods from a food safety point of view;
- E.g., increasing produce consumption, increasing spice usage to reduce sodium in foods,
  - Produce and spices frequently consumed ready-to-eat, with large proportion imported;
- FDA augments our usual inspection and compliance work by doing innovative regulatory science to help **PREVENT** outbreaks and **SOLVE** them earlier.

Research

- Development and validation of analytical methods for a wide variety of targets:
  - ✓ Allergens, food pathogens, food additives, dietary supplements, seafood toxins, industrial chemicals in CFSAN - regulated food and cosmetic products, and many others;
- Consumer studies/surveys;

Research (cont.)

- Toxicology
  - ✓ Development of *in vitro* and *in vivo* screening models for hepatotoxicity, renal toxicity, cardiotoxicity and neural toxicity
- Contribution to risk assessment, policy development, compliance programs, international standards development, ex. CODEX

Other Initiatives

Dietary Supplements

Setting up the new Office of Dietary Supplements

Cosmetics

Request for new legislative authority

Dietary Supplements

Elevation from Division to Office

- Reflects increased size and scope of the dietary supplement industry
- Allows for:
  - Greater visibility, both inside and outside FDA
  - Improved ability to influence and direct FDA's dietary supplement program resources
  - Opportunity for enhanced external partnerships with federal and state agencies, academia, industry, consumers, healthcare providers, etc.

Dietary Supplements

- **Number one priority is consumer safety**
  - Protect consumers from dangerous products

- Be proactive
  - Ensure the integrity of product identity
  - Enhance CGMP compliance through enforcement and education
  - Make sure consumers and health care practitioners have access to information that lets them make informed choices
  - Evaluate the need for greater FDA guidance in certain areas

Dietary Supplements

Recent Enforcement Actions

- Warning Letters:
  - Methylsynephrine
  - *Acacia rigidula*
  - Picamilon
  - CGMP
- Kratom (seizure following ADO)
- Injunction cases

Dietary Supplements

CFSAN will continue to:

- Monitor the safety of dietary supplement products
- Take action to remove from the market supplement products that are dangerous to consumers
- Take action against claims in cases involving serious risk of harm to the consumer (such as egregious claims of benefit in treating serious diseases) or widespread economic fraud
- Enforce the dietary supplement good manufacturing practices (GMP) regulation

Enhance Operational Excellence

- Recruit/Appoint Senior Leaders:
  - Director, Office of Dietary Supplement Programs
  - Director, Office of Analytics and Outreach
  - CFSAN Senior Science Advisor
- Succession planning