

To: Our Clients and Friends

May 14, 2010

## Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



### Top News

#### **IOM Report Recommends Framework for Evaluating Science Behind Health Claims, Says Tougher Standards Needed for Foods and Dietary Supplements**

On May 12, 2010, the [Institute of Medicine \(IOM\)](#) released a consensus report, titled *Evaluation of Biomarkers and Surrogate Endpoints in Chronic Disease*. The report recommends that FDA should apply the same rigor to evaluating the science behind claims of foods' and nutritional supplements' health benefits as it devotes to assessing medication and medical technology approvals, citing that there is no reason to apply different standards as both are important to health. IOM noted that "it is important to realize that health claims on foods potentially impact a far greater portion of the population than do drug claims." The proposed framework entails validating that a biomarker can be accurately measured, ensuring that it is associated with the clinical outcome of concern, and confirming that it is appropriate for the proposed use.

#### **FDA Warning Letters On the Rise**

Warning letters issued by FDA have been steadily on the rise and the trend is continuing into 2010. FDA has sent 186 warning letters so far this year, which puts the agency on track to match or exceed the 570 warning letters issued in 2009, a historic year for FDA, which issued only 436 warning letters in 2008 and 381 in 2007. For food products, FDA has stepped up enforcement efforts by issuing warning letters to companies whose products are, according to FDA, misbranded because the products contain unsubstantiated claims or are otherwise not properly labeled. Other common violations in warning letters to food manufactures include HACCP and GMP violations, as well as "offering for sale an animal for slaughter as food that was adulterated."

#### **Task Force Unveils Action Plan to Solve Childhood Obesity Within A Generation**

On May 11, 2010, the Childhood Obesity Task Force unveiled its action plan: [Solving the Problem of Childhood Obesity Within a Generation](#). In conjunction with the release of the action plan, Cabinet Members and Administration Officials will hold events across the country to highlight the importance of addressing childhood obesity. [USA Today](#) and the [Washington Post](#) reported on the issue and USDA issued a [press release](#) describing the report.

## Officials Confirm Link Between Bagged Romaine Lettuce and E. Coli O145 Outbreak

Federal and state officials have confirmed a link between bagged romaine lettuce and E. Coli outbreak. FDA, along with CDC and its state health partners, have confirmed that the strain of E. coli O145 detected by the New York State Public Health Laboratory, in an unopened bag of shredded romaine lettuce distributed by Freshway Foods, matches the outbreak strain of E. coli O145. Officials continue to investigate the outbreak.

## FSIS Issues Public Health Alert for Various Ready-To-Eat Prosciutto Deli Meats

USDA's Food Safety and Inspection Service (FSIS) issued a public health alert for various ready-to-eat deli meat products because they may be contaminated with *Listeria monocytogenes*. FSIS was notified by the Canadian Food Inspection Agency that various Casa Italia and Emma ready-to-eat prosciutto deli meat products that are subject to recall in Canada may have been exported to the United States.

## FDA Says Some Supplement Firms Will Not Meet GMP Final Rule Deadline

June 25, 2010 is the final deadline for the three-year phase in of good manufacturing practices (GMPs) final rule. However, according to FDA's Division of Dietary Supplement Programs, some small- and medium-sized firms are unlikely to meet the deadline.

## Briefly Noted

Public health regulators in Massachusetts are concerned that a BPA ban may make matters worse because replacement substances might be more toxic.

Food allergy data called into question due to lack of high-quality studies.

Candy tax to go into effect in Washington state beginning June 1, 2010.

## Recent Recalls

Baroody Dried Apricots due to undeclared sulfites (May 12, 2010).

BIGS Original Salted & Roasted Sunflower Seeds due to undeclared dairy ingredients (May 12, 2010).

Galant Food Co. chicken and beef puff products due to undeclared egg (May 12, 2010).

## Recently Posted Warning Letters

FDA warned Martin Feed Lot, Elma Dairy, LLC, and Land Dairy, Inc. that FDA investigators found that the firms offered for sale animals for slaughter as food that was adulterated due to the presence of drug residues in the animals' tissues.

FDA warned Olsen Fish Company and Noxubee County Producers, Inc. that an FDA inspection documented serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation that renders the firms' fish or fishery products adulterated.

FDA warned Darr Feedlots, Inc. that FDA inspectors documented the use of animal drugs in a manner that was not consistent with FDA approval as well as significant deviations from current Good Manufacturing Practice, which cause the medicated feed produced by the firm to be adulterated.

FDA warned www.tcmhelpme.com, an internet web site that sells herbal remedies, that its products were being illegally marketed because their web sites offered a product for sale that is intended to diagnose, mitigate, prevent, treat (including to treat the symptoms of) or cure the H1N1 Flu Virus in people, although the products have not been approved or otherwise authorized by FDA for such use.

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## ***New Regulatory Notices***

### **FSIS Updates**

FSIS recently published the following revised export requirements and plant lists:

- [Japan \(Cold Storage Facilities\)](#) (May 13, 2010)
- [South Africa Plant List](#) (May 13, 2010)

FSIS recently published a new notice:

- [FSIS Notice 25-10](#) *Interpreting Results of FSIS Verification Sampling of Beef Product Derived from Advanced Meat Recovery Systems (AMR01/FAMR01)*

## ***Regulatory Notices with Open Comment Periods***

### **FDA Requests Comments on Prior Notice of Imported Food Information Collection**

FDA published a [Federal Register Notice](#) to solicit comments on the information collection provisions of FDA's regulations requiring that the agency receive prior notice before food is imported or offered for import into the United States. Interested parties must submit electronic or written comments by **May 17, 2010**.

### **FDA Requests Comments on Reportable Food Registry Information Collection**

FDA published a [Federal Register Notice](#) to solicit comments on the information collection provisions of the agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Interested parties must submit electronic or written comments by **May 17, 2010**.

### **FDA Requests Comments on Cosmetics Labeling Information Collection**

FDA published a [Federal Register Notice](#) to solicit comments on information collection provisions in FDA's cosmetic labeling regulations. Interested parties must submit electronic or written comments by **May 17, 2010**.

### **FSIS Seeks Comments on New Rules to Enhance Food Safety**

USDA Food Safety and Inspection Service (FSIS) is [proposing to implement provisions of the Food, Conservation, and Energy Act of 2008 \(2008 Farm Bill\)](#) by adopting regulations that require official establishments to promptly notify the appropriate District Office that an adulterated or misbranded meat or poultry product has entered commerce; require official establishments to prepare and maintain current procedures for the recall of meat and poultry products produced and shipped by the establishment; and require official establishments to document each reassessment of the establishment's process Hazard Analysis and Critical Control Point plans. The notice was published in the [March 25, 2010 Federal Register](#). Interested parties must submit electronic or written comments by **May 24, 2010**.

### **FDA Announces Food Additive Petition for Animal Use of Erythromycin Thiocyanate**

In the [April 23, 2010 Federal Register](#), FDA announced that North American Bioproducts Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient. Interested parties must submit written or electronic comments on the petitioner's environmental assessment by **May 24, 2010**.

## **FDA Reopens Comment Period on Quality Standard for Bottled Water**

On April 1, 2010, FDA reopened until June 1, 2010 the comment period for the proposed rule, published in the August 4, 1993 Federal Register, amending the quality standard for bottled water (found at 21 CFR 165.110(b)). Additional information is available in the [Federal Register Notice](#). Electronic or written objections and requests for a hearing may must be submitted by **June 1, 2010**.

## **FDA Seeks Comments on Information Collection for Firms Exporting to Countries that Require an Export Certificate as a Condition of Entry for FDA-Regulated Products**

In the [March 31, 2010 Federal Register](#), FDA issued a notice of information collection seeking comments on information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA-regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act as amended. Electronic or written objections and requests for a hearing may must be submitted by **June 1, 2010**.

## **FDA Information Collection Concerning Guidance for Industry on Submitting A Notice of Intent to Slaughter for Human Food Purposes in Electronic Format**

In the [April 30, 2010 Federal Register](#), FDA announced that it has submitted a proposed collection of information concerning guidance for industry on submitting a notice of intent to slaughter for human food purposes in electronic format to the Office of Management and Budget (OMB) for review and clearance under the paper work reduction act. Interested parties must submit written or electronic comments by **June 1, 2010**.

## **FDA Announces Proposed Information Collection on Consumers' Knowledge and Behavior During Foodborne Illness Outbreaks or Food Recalls**

In the [May 4, 2010 Federal Register](#), FDA announced a proposed collection of information concerning a real-time survey of consumers knowledge an perceptions, as well as reported behavior, during foodborne illness outbreaks or food recalls, has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. Interested parties must submit written or electronic comments by **June 3, 2010**.

## **FDA Issues Notice and Request for Comments on Bisphenol-A Safety Assessment**

In the [April 5, 2010 Federal Register](#), FDA announced the availability of five documents related to FDA's continuing assessment of Bisphenol A (BPA) and soliciting public comments on the four documents prepared by FDA's Center for Food Safety and Applied Nutrition (CFSAN). These documents do not represent an agency opinion or position on BPA, on which an [interim update](#) was recently provided. Rather, these documents provide perspectives and opinions that are being considered by FDA as it continues its safety assessment of BPA. This action will enable FDA to consider comments from the public in its assessment of BPA for food contact applications. Written or electronic information and comments must be submitted by **June 4, 2010**. More information is available in the [Federal Register Notice](#).

## **FDA Seeks Comments on Information Collection Provisions for Fish Processors**

In the [April 9, 2010 Federal Register](#), FDA announced a notice of information collection that also solicits comments on the information collection provisions of FDA's regulations requiring reporting and recordkeeping for processors and importers of fish and fishery products. Written or electronic information and comments must be submitted by **June 8, 2010**.

## **FDA Seeks Comments on Requests for Exemption from Food Additive Listing Regs**

In the [April 9, 2010 Federal Register](#), FDA announced a notice of information collection that also solicits comments on requests for exemption from the food additive listing regulation requirements that are submitted under part 170 (21 CFR part 170). Written or electronic information and comments must be submitted by **June 8, 2010**.

## **FDA Seeks Comments on Collection of Information on Food Code Implementation**

In the [April 14, 2010 Federal Register](#), FDA announced it is soliciting comments on the collection of information from local, State, and tribal governmental agencies concerning their adoption of, or plans to adopt, all or portions of the FDA Food Code or its equivalent by regulation, law, or ordinance. Written or electronic information and comments must be submitted by **June 14, 2010**.

## **FSIS Extends Comment Period for HACCP Systems Validation Documents**

In March, FSIS made available three documents on the validation of HACCP systems on its Web site at [http://www.fsis.usda.gov/PDF/HACCP\\_Validation\\_Ltrs.pdf](http://www.fsis.usda.gov/PDF/HACCP_Validation_Ltrs.pdf) (PDF Only). The comment period has been extended to **June 19, 2010**. Interested parties should submit their comments to [DraftValidationGuideComments@fsis.usda.gov](mailto:DraftValidationGuideComments@fsis.usda.gov), or mail comments to the Docket Clerk, USDA, FSIS, George Washington Carver Center, Room 2-2127, 5601 Sunnyside Ave., Beltsville, MD 20705. The agency will review comments received and decide how it will proceed with respect to the validation of HACCP systems.

## **FDA Requests Comments and Data to Inform Risk Profile for Pathogens in Spices**

In the [April 20, 2010 Federal Register](#), FDA issued a request for comments and scientific data and information that would assist the agency in its plans to conduct a risk profile for pathogens and filth in spices. The purpose of the risk profile is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current and potential new interventions to reduce or prevent illnesses from contaminated spices. Interested parties must submit electronic or written comments and scientific data and information by **June 21, 2010**.

## **FDA Seeks Comments on Proposed Information Collection on Infant Formula**

In the [May 4, 2010 Federal Register](#), FDA announced that it is soliciting comments on information collection regarding the manufacture of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping. Interested parties must submit written or electronic comments by **July 6, 2010**.

## **FDA Issues Advance Notice of Proposed Rulemaking to Implement 2005 SFTA**

In the [April 30, 2010 Federal Register](#), FDA announced an advance notice of proposed rulemaking to implement the Sanitary Food Transportation Act of 2005 (2005 SFTA, see top news story above). FDA is specifically requesting data and information on the food transportation industry and its practices. FDA also is requesting data and information on the contamination of transported foods and any associated outbreaks. FDA is taking this action as part of its implementation of the 2005 SFTA, which requires the Secretary of HHS to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. This action is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. The regulations would address the risks to human or animal health associated with the transportation of food. Interested parties must submit electronic or written comments by **August 30, 2010**.

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## ***Upcoming Meetings***

### **USDA to Hold Meat and Poultry Inspection Seminars for International Officials**

**Between May 18 and June 4, [USDA will host the first of three meat and poultry inspection seminars for international officials](#)** in Puerto Rico. The purpose of the seminars is to familiarize international government officials with U.S. inspection regulations and procedures used by USDA to assure that the nation's meat, poultry and egg products are safe, wholesome and properly labeled. This seminar will be conducted in Spanish and participation is limited. USDA has a [web page with more information and registration](#). Additional seminars will be held in August and September.

## USDA Announces Meeting to Discuss U.S. Positions for Codex Meeting

On Tuesday, **June 8, 2010**, USDA's Office of Food Safety is sponsoring a [public meeting to provide information and receive public comments on agenda items and draft U.S. positions](#) that will be discussed at the 33rd Session of the Codex Alimentarius Commission (CAC), to be held in Geneva, Switzerland, July 5-9, 2010.

## FDA Announces Food Protection Workshop

FDA's Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in cosponsorship with the University of Arkansas (UA) Institute of Food Science and Engineering, is announcing "Food Protection Workshop," a public workshop to provide information about food safety, food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and other related subjects to the Food Protection Plan as it relates to food establishments such as farms, manufacturers, processors, distributors, retailers, and restaurants. This public workshop will be held on **June 9 and 10, 2010**. Additional information is available in the [Federal Register Notice](#) announcing the workshop.

## 2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System

In the [April 2, 2010 Federal Register](#), FDA announced a public meeting entitled "2010 Scientific Meeting of the National Antimicrobial Resistance Monitoring System." The meeting will discuss results from the National Antimicrobial Resistance Monitoring System (NARMS) and related antimicrobial resistance monitoring and research, including activities in other national programs. The public meeting will be held on **July 15 and 16, 2010** in Atlanta, Georgia. Interested parties may submit written comments to the docket up to 30 days after the meeting. Additional information, including about registration, requests for oral presentations, and the meeting agenda, is available in the [Federal Register Notice](#).

## USDA Workshops to Explore Competition and Regulatory Issues

**Between March 12 and December 8, 2010**, the Department of Justice and USDA will hold [five joint public workshops that will explore competition and regulatory issues in the agriculture industry](#). The workshops target issues of concern to farmers and the poultry, dairy, livestock industries. The final workshop will focus on price margins.

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## More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at [www.bryancave.com](http://www.bryancave.com) on the [FDA Practice Bulletins web page](#). If you have any questions regarding any of these issues, please contact:

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