To: Our Clients and Friends  August 27, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin

Top News

FDA Announces Details on New Federal Menu Labeling Requirements
On August 24, 2010, FDA released two guidance documents that outline steps to help certain chain restaurants and vending machine companies comply with new federal nutrition labeling requirements (which were included in the new health care reform law passed in March):

Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010;

and

Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws.

The purpose of the documents is to inform affected businesses of what is required by the menu labeling provisions as FDA moves toward publishing a proposed rule on menu labeling in March 2011. FDA asserts that menu labeling will ultimately provide more complete information for consumers so that they can make better choices about what they eat at various eating establishments and when using vending machines.

FDA is accepting comments on both guidances. Although interested parties may comment on any guidance at any time, to ensure that comments receive agency consideration before FDA begins work on the final version of the draft guidance, interested parties must submit electronic or written comments by October 12, 2010. Links to the federal register notices and other helpful information are available on FDA’s web page on New Menu and Vending Machines Labeling Requirements.

Urgent Nationwide Egg Recall Continues; Senate Urged to Pass Food Safety Bill
An outbreak of Salmonella Enteritidis (SE) that has sickened hundreds of people across the country has led to a recall of shell eggs. FDA issued a news release on August 19, 2010 with details about the egg recall, the associated SE outbreak and interagency efforts to address the problem. The New York Times reported on the issue and featured it in its Room for Debate column. A Politico editorial questions whether the Senate’s failure to pass food safety legislation is to blame for yet another major recall.
FDA Testifies at Hearing Before Subcommittee on Energy and Environment
On Ensuring the Safety of Seafood from the Gulf
On August 19, 2010, Donald Kraemer, Acting Deputy Director of the Center for Food Safety and Applied Nutrition at FDA, testified before the House Committee on Energy and Commerce Subcommittee on Energy and Environment. His testimony discussed FDA's role in ensuring the safety of seafood harvested from waters in the Gulf of Mexico in the wake of the Deepwater Horizon oil spill and touched on closures, surveillance, testing for reopening, reopenings, and additional testing and research. He concluded by saying that consumer safety is FDA's number one priority and they continue to work closely with other federal and state agencies to proactively monitor the disaster and ensure a safe food supply.

Dr. Elisabeth Hagen Sworn in as USDA Undersecretary for Food Safety
In a recess appointment, President Obama appointed Dr. Elisabeth Hagen to serve as the USDA Undersecretary for Food Safety. She was sworn in on August 20, 2010, and USDA Secretary Tom Vilsack issued a statement saying that "there is no higher priority at USDA than ensuring that Americans have access to a safe and healthy food supply." Although not considered a controversial candidate, her nomination had not progressed to a vote in the Senate.

New York Times Examines Suggestions for Remaking Food Labels
In it's Well column, the New York Times examines the Center for Science in the Public Interest's (CSPI) suggestions for giving the Nutrition Facts panel a makeover. FDA is currently considering how to make nutrition labeling more useful for consumers, particularly through enhanced nutrition facts and front-of-pack labeling.

Canada to Add BPA to Its Toxic Register
Environment Canada said this week that it expects "to conclude the process of having bisphenol A added to the List of Toxic Substances in Schedule I of the Canadian Environmental Protection Act,1999 (CEPA, 1999) in 8-10 weeks."

Government Releases Assessment of Potential Food Risks Posed by Bird Flu Virus
On August 20, 2010, the Federal Government released an assessment of potential food risks posed by highly pathogenic avian virus (HPAIV, commonly called bird flu), providing health authorities and others with a science-based approach to preventing human illness from the virus.

U.S. Marshals Seize Food From Rodent Infested Georgia Warehouse
On August 19, 2010, U.S. Marshals, acting under a court order sought by FDA, seized packaged food products from a rodent-infested warehouse in Athens, Ga. A variety of products, including crackers, cookies and potato chips, were intended for sale to jails and prisons throughout the southeastern United States.

Briefly Noted
Egg Industry Faces New Scrutiny After Outbreak

Recent Recalls
Firms that are recalling eggs due to possible Salmonella contamination include:

- Cal-Maine Foods (August 26, 2010).
- Moark, LLC (August 23, 2010).
- NuCal Foods (August 20, 2010).
- Luberski Inc. (August 20, 2010).
- Hillandale Farms (August 20, 2010).
- Country Eggs (August 19, 2010).
Other recalls include:

- **Natural Wellness MasXtreme supplement** due to presence of active drug ingredient (August 24, 2010).
- **Azteca Linda Corp. Queso Fresco and Queso Hebra** due to possible Listeria contamination (August 24, 2010).
- **Zemco Industries deli meat products** due to Listeria contamination (August 23, 2010).
- **Milton's Baking 24 oz. Multi-Grain Bread** due to undeclared milk (August 20, 2010).
- **GloryBee Foods whole raw pistachio products** due to possible Salmonella contamination (August 20, 2010).
- **Austinuts Wholesale pistachio kernel products** due to possible Salmonella contamination (August 19, 2010).
- **Snow White Food Products Inc. alfalfa sprouts** due to Salmonella contamination (August 19, 2010).

Recently Posted Warning Letters

FDA warned **Ken Corscadden** that an investigation of his dairy in New York found that he offered for sale animals for slaughter as food that were adulterated.

FDA warned **Amish Wedding Foods Inc.** that FDA inspectors found serious deviations from the low-acid food regulations.

FDA warned **Fiesta Gourmet and Deli** and **Gropoint Seafood Industries Sdn Bhd** that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

New Regulatory Notices

**FDA Seeks Comments on New On Federal Menu Labeling Requirements Guidances**

In the August 25, 2010 Federal Register, FDA issued notices seeking comments on two new guidances concerning the new federal menu labeling requirements. The notices concern:


Links to the guidance documents and other helpful information are available on [FDA’s web page on New Menu and Vending Machines Labeling Requirements](http://www.fda.gov). Although interested parties may comment on any guidance at any time, to ensure that comments receive agency consideration before FDA begins work on the final version of the draft guidance, interested parties must submit electronic or written comments by **October 12, 2010**.

**FDA Announces Public Hearing on GM Salmon**

In the **August 26, 2010 Federal Register**, FDA announced that it will hold a public hearing regarding the labeling of food derived from AquAdvantage Salmon (a genetically engineered Atlantic salmon) on September 21, 2010, from 9 a.m. to 4:30 p.m. in Rockville, MD. The purpose of the hearing is for FDA to explain the relevant legal principles for food labeling and to solicit information and views from interested persons on the application of these principles to the labeling of food derived from AquAdvantage Salmon. In a separate notice published elsewhere in this issue of the Federal Register, FDA is announcing that it will hold a public Veterinary Medicine Advisory Committee (VMAC) meeting. Advance registration is required by September 13, 2010. For additional information, see the [Federal Register Notice](http://www.fda.gov).

**USDA Requests Extension for Advanced Meat Recovery Information Collection**

In the **August 20, 2010 Federal Register**, USDA announced its intention to request an extension of an approved information collection regarding the regulatory requirements associated with the production of meat from Advanced Meat Recovery Systems. Interested parties must submit comments by **October 19, 2010**.
FSIS Policy Updates

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

- **Mexico Plant List** (Aug 26, 2010)
- **Russia Plant List, Pork** (Aug 26, 2010)
- **Mexico** (Aug 24, 2010)
- **Australia Plant List** (Aug 19, 2010)

Regulatory Notices with Open Comment Periods

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

In the [April 30, 2010 Federal Register](http://example.com), FDA announced an advance notice of proposed rulemaking to implement the Sanitary Food Transpiration Act of 2005. FDA is specifically requesting data and information on the food transportation industry and its practices, as well as data and information on the contamination of transported foods and associated outbreaks. 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**.

**USDA Announces Notice of Request for Revision of a Currently Approved Information Collection (Pathogen Reduction/HACCP)**

In the [June 29, 2010 Federal Register](http://example.com), USDA announced that it is revising the Pathogen Reduction/HACCP systems information collection based on its most recent establishment data. In addition, FSIS is adding information concerning the use of video recordkeeping for HACCP records and Sanitation Standard Operating Systems (SOPs) records. Interested parties must submit comments by **August 30, 2010**.

**FDA Seeks Public Input on Restaurant Menu Labeling**

In the [July 7, 2010 Federal Register](http://example.com), FDA invited the public to submit comments and information to help the agency implement a new federal law that requires the posting of calorie content and other nutrition information on menu items at certain chain restaurants and similar retail food operations and vending machines. FDA has opened a docket to gather comments and information. The new law, part of health care reform, requires restaurants and chain retail food establishments with 20 or more locations to list calorie content information on menus and menu boards, including drive-through menu boards. More information is available on the web site for Docket No. FDA-2010-N-0298 and on FDA’s web site. Written or electronic comments must be received by **September 7, 2010**.

**FSIS Seeks Comments on Proposed Amendments to Meat/Poultry/Egg Regulations**

In the [August 9, 2010 Federal Register](http://example.com), USDA’s Food Safety and Inspection Service (FSIS) proposed to amend the meat, poultry products, and egg products regulations pertaining to the schedule of operations. FSIS is proposing to amend these regulations to define the 8-hour work day as including time that inspection program personnel need to spend at the workplace donning and doffing required gear, time spent walking to their workstations after donning required gear, and time spent walking from their work stations prior to doffing required gear. FSIS is amending these regulations to ensure effective and prudent expenditure of Agency budgetary and other resources while administering its inspection program in accord with the Supreme Court's holding in IBP, Inc. v. Alvarez, 546 U.S. 21 (2005) and policy guidance from the Office of Personnel Management. Interested parties must submit comments on or before **September 8, 2010**.

**FDA Seeks Comments on Information Collection for CGMPs for Dietary Supplements**

In the [July 14, 2010 Federal Register](http://example.com), FDA announced an opportunity for public comment on an information collection for Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. Interested parties must electronic or written comments by **September 13, 2010**.
FDA Seeks Comments on Information Collection for Juice HACCP
In the July 14, 2010 Federal Register, FDA announced an opportunity for public comment on an information collection concerning Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice. Interested parties must electronic or written comments by September 13, 2010.

FDA Seeks Comments on Information Collection for Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients
In the July 20, 2010 Federal Register, FDA announced an opportunity for public comment on an information collection concerning a petition to request an exemption from 100 percent identity testing of dietary ingredients: current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements. Interested parties must electronic or written comments by September 20, 2010.

FSIS Requests Revision of Approved Information Collection on SRMs in Cattle
In the July 23, 2010 Federal Register, USDA announced the Food Safety and Inspection Service’s (FSIS) intention to request revision of an approved information collection regarding specified risk materials (SRMs) in cattle because the OMB approval will expire on January 31, 2011, and to incorporate another approved information collection, Specified Risk Materials—Transport. Comments on this notice must be received on or before September 21, 2010.

FDA Announces Information Collection Regarding Pet Event Tracking Network—State, Federal Cooperation to Prevent Spread of Pet Food Related Diseases
In the July 27, 2010 Federal Register, FDA announced that it is conducting an information collection concerning its plans to implement an initiative called “The Pet Event Tracking Network” (PETNet) that will allow FDA and its State partners to quickly and effectively exchange information about outbreaks of illness in companion animals associated with pet food. The PETNet proposal was developed in response to the 2007 outbreak that occurred in companion animals that was associated with the deliberate adulteration of pet food components, such as wheat gluten, with melamine. As envisioned by the subgroup at that time, PETNet would include a system for reporting outbreaks and would be supported by adequate diagnostic laboratory facilities and an established mechanism for conducting national epidemiological investigations. Submit either electronic or written comments on the collection of information by September 27, 2010.

FDA Announces Draft Guidance on Prevention of Salmonella in Shell Eggs
In the August 12, 2010 Federal Register, FDA announced the availability of a Draft Guidance titled, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation. Interested parties should submit comments by October 12, 2010.

FDA Announces Proposed Information Collection on Microbial Food Safety Hazards

FDA Announces Information Collection From U.S. Processors That Export to the EC
In the August 18, 2010 Federal Register, FDA announced that it is requesting information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. Interested parties may submit either electronic or written comments on the collection of information by October 18, 2010.

FDA Details Voluntary Compliance with New Federal Menu Labeling Requirements
FDA Announces In the July 23, 2010 Federal Register, FDA issued a notice giving details on how retail food establishments and vending machine operators with fewer than 20 locations can choose to become subject to the new
federal menu labeling requirements. CFSAN’s Constituent Update and provides additional details. Interested parties must submit electronic or written comments by October 21, 2010.

FDA Announces New CPG for Salmonella in Animal Feed
In the August 3, 2010 Federal Register, FDA announced the availability of a draft guidance for FDA staff entitled Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed (the draft CPG). The draft CPG, when finalized, is intended to provide guidance for FDA staff on regulatory policy relating to animal feed or feed ingredients that come in direct contact with humans, such as pet food and pet treats, contaminated with Salmonella and also on regulatory policy relating to animal feed or feed ingredients contaminated with a Salmonella serotype that is pathogenic to the target animal for the animal feed. Interested parties may comment on CPG documents at any time, however, to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by November 1, 2010.

Upcoming Meetings

USDA to Hold Meeting Addressing Codex Committee on Processed Fruits, Veggies
On August 18, 2010, USDA announced a public meeting to provide information and receive comments on agenda items and draft U.S. positions that will be discussed at the 25th Session of the Codex Committee on Processed Fruits and Vegetables (CCPFV), to be held in Denpasar, Indonesia, Oct. 25 - 29, 2010. The public meeting is scheduled for Monday, Aug. 30, 2010, from 10:00 a.m. to 12:00 p.m., in Room 2068, USDA, South Building, 1400 Independence Avenue, SW, Washington, DC. To participate through teleconference, dial (888) 996-4918, and enter the passcode 63757. A complete agenda and documents relating to the 25th Session of CCPFV will be available on the Codex Alimentarius Web site at www.codexalimentarius.net/current.asp.

USDA Designs Inspection Seminars for International Government Officials
USDA will host the third of three meat and poultry inspection seminars for international officials in Washington, D.C., from September 13 – October 1, 2010. The 2-week, in-depth seminar will be in English and will focus on verification and enforcement of HACCP and pathogen reduction regulations in order to familiarize participants with U.S. inspection regulations and procedures used by USDA to ensure that the nation’s meat, poultry and egg products are safe, wholesome and properly labeled. For more information and to register, visit http://www.fsis.usda.gov/news_&_events/2010_Meat_&_Poultry_Inspection_Seminars/index.asp.

FSIS, CDC, FDA to Hold Public Meetings on Measuring Food Safety Progress
Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), are jointly hosting two public meetings to obtain stakeholder input. The first was on July 21, 2010, in Chicago, IL. The second will be held on October 20, 2010, in Portland, OR. The Agencies are requesting information from all stakeholders, including the regulated food industry, State regulators, and consumer groups, on appropriate metrics to be used to assess performance in food safety. The Agencies are also interested in input on stakeholders' understanding and perceptions of metrics currently being used by the Federal Agencies. Although the Agencies are primarily interested in obtaining stakeholder input, the Agencies will present a limited amount of background on the Food Safety Working Group’s charge to create meaningful metrics to measure the effectiveness of the Nation's food safety system and the Agency's current thinking on these issues. More information 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.

More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at 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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