To: Our Clients and Friends  

September 9, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin

**Top News**

**FDA Launches New Performance Management System to Further Transparency**

On August 31, 2010, FDA launched an innovative performance management system designed to advance the President’s commitment to transparency, public participation, and collaboration in the work of government. The system, called FDA-TRACK, will monitor more than 100 FDA program offices through data from key performance measures established each year. That data will be gathered monthly, analyzed and presented each quarter to FDA senior leadership. Importantly, the public will be able to track this data and the agency’s progress through the FDA-TRACK website.

**China Destroys and Blocks Food and Cosmetic Imports Over Safety Concerns**

China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) announced on its web site that certain products from the United States, Japan, and New Zealand, among other nations, “have been returned, destroyed or converted to other uses” and “were not sold in the domestic market.” Although since the melamine scandal (where milk and infant formula products were found to be tainted with melamine, an industrial chemical), the Chinese government has repeatedly announced its efforts to improve food safety. However, even in the mist of drastic measures such as blocking food imports from industrialized nations known to have safe food programs, there are reports that tainted melamine products keep surfacing in China.

**Tainted Feed and Poor Sanitation Suspected of Spreading Salmonella at Egg Farms**

FDA believes that contaminated chicken feed is likely responsible for the recent salmonella outbreak that has been tied to recalled shell eggs. FDA has published the inspection reports completed during the dates of the egg recall at both the Quality Egg facility and Hillandale Farms facilities. The Los Angeles Times, New York Times, and Washington Post have all reported on the issue. To ensure that farms are complying with the new rules related to shell eggs, FDA will inspect facilities where 80 percent of the country’s eggs are produced over the next 15 months.
FDA Warns About Green Tea Products’ “Enhanced” Antioxidant and “Drug” Claims
FDA recently issued warning letters to two producers of green tea products citing that the product labels and web sites contained impermissible claims. In a warning letter to Dr Pepper Snapple Group, FDA noted that the product was in violation of FDA laws because of claims that the beverage was "enhanced" with antioxidants and the product violated the FDA’s fortification policy. In another letter to Unilever, FDA said that its Lipton Green Tea 100% Naturally Decaffeinated product is in violation of FDA laws because the product label displays unauthorized nutrient content claims and that the marketing of the product on the web site includes claims related to conditions that cause the product to be a drug (similar to FDA's warning to Cheerios about cholesterol claims). The letter demonstrates that FDA is continuing its enforcement trend of cracking down on labeling claims (which includes claims made on a web site if the web site is referenced on the label), and continues to pay special attention to antioxidant and “drug” claims.

USDA Will Issue New Rules on Biotech Sugar Beets This Year
On September 1, 2010, USDA’s Animal and Plant Health Inspection Service (APHIS) announced the next steps in response to a recent court decision on Roundup Ready sugar beets. APHIS has received applications from and is issuing permits to sugar beet seed producers to authorize "steckling" (i.e seedlings) production this fall under strict permit conditions that would not allow flowering of the stecklings. In response to the request for a partial deregulation of Roundup Ready sugar beets, APHIS plans to make decisions on interim measures by the end of the year. For the final decision, APHIS is developing an appropriate environmental analysis to inform its decision making (which will be made available for public comment). Any regulatory measures taken would include mitigating restrictions consistent with those proposed to the Court as interim measures while APHIS completes the environmental impact statement (EIS) for the petition for determination of non-regulated status for GE sugar beets. APHIS will continue to place a priority on the expedited completion of the EIS, a process that is anticipated to take 2 years. The New York Times also reported on the issue.

FTC Issues Subpoenas About Kids Marketing Practices to 48 Food Companies
In order to measure the outcomes of self-regulation over the last three years, FTC has issued subpoenas to 48 firms, many of them food companies, requiring them to provide information on their child marketing practices. FTC will use the information to prepare a follow-up to their 2008 report, "Marketing Food to Children and Adolescents: A Review of Industry Expenditures, Activities and Self-Regulation."

FDA Seeks Court Order Against Michigan Dairy, Alleges Illegal Drug Residues
On behalf of FDA, the U.S. Department of Justice has filed a complaint for permanent injunction against Scenic View Dairy of Hamilton, Mich., its president, and three of its managers alleging that they sold dairy cows for human consumption that contained illegal drug residues in edible tissues. The complaint also alleges that the defendants, despite numerous warnings, sold for slaughter dairy cows that were treated with drugs contrary to the drugs’ FDA-approved labeling and without a valid veterinary prescription authorizing such use.

FSIS to Host Public Health Information System (PHIS) Webinars
USDA’s Food Safety and Inspection Service (FSIS) will host a series of webinars to introduce a new FSIS comprehensive data system called the Public Health Information System (PHIS) as part of its effort to collect, consolidate and analyze data. The presentations will be an overview of PHIS and cover three separate topics: what it means to owners/operators of domestic establishments, how it will affect export certifications and requirements for import certification. Additional information on the webinars and how to register area available on USDA’s web site.

Briefly Noted
The New York Times Reports "In Feast of Data on BPA Plastic, No Final Answer."
Canada expresses concerns over EU proposal to allow member states to decide on GM crops.
Judge Recommends PCA pay out $12 million to settle the 120 claims arising out of salmonella tainted peanut butter.
American Beverage Association spent almost $4 million on anti-tax lobbying in second quarter of 2009.
FSIS Reaches Out To Spanish-Speaking Consumers with the Launch of New Online Tools.
 USDA will purchase up to $30 million of chicken dark meat items for federal food nutrition assistance programs.
 California Senate throws out bill banning BPA.
 FSIS Reaches Out to Spanish-Speaking Consumers with the Launch of New Online Tools.
 UK Food Standards Agency announces new labeling responsibilities.
 Polymer coating might be new alternative to BPA in lining epoxy cans.
 Researchers say that those who read food labels make healthier food choices.
 Canadian Food Inspection Agency finds many food labeling claims are untrue.
 Intelligent shelf-life indicator could help improve accuracy of shelf life, prevent food waste.

Recent Recalls
FDA Issues Alert on Milk Products due to improperly pasteurized milk (September 8, 2010).
FDA Issues Alert on All Estrella Family Creamery Cheeses due to potential Listeria contamination (September 4, 2010).
Real Taste Noodle Egg Noodles due to potential Salmonella contamination (September 3, 2010).
Sparboe Farms clarification on shell egg recall due to Salmonella contamination (September 3, 2010).
Hartz Naturals Real Beef Treats for Dogs due to potential Salmonella contamination (September 3, 2010).
Whole Foods Market's Morningland Dairy and Ozark Hills Farm Raw Goat Milk Mild Cheddar Cheese due to possible Listeria and Staphylococcus aureus contamination (September 2, 2010).
Cibo Vita Mediterranean Mix of Woodpecker brand due to undeclared sulfites (September 1, 2010).
Azteca Linda Requeson and Queso Fresco due to potential Listeria contamination (September 1, 2010).
Trinh Company cooked shredded pork skin products due to lack of inspection (September 1, 2010).
Iams Indoor Weight Control with Hairball Care dry cat food due to potential Salmonella contamination (August 31, 2010).
Morningland Dairy cheese due to potential Listeria contamination (August 30, 2010).
Cargill Meat Solutions ground beef products due to potential E. coli contamination (August 28, 2010).
Queseria Chipilo Recalls Cheese Products due potential Listeria contamination (August 27, 2010).
Paleta California Mamey Supreme Cream Bar due to potential Salmonella contamination (August 27, 2010).
Sparboe Farms Shell Eggs due to Salmonella contamination (August 27, 2010).
Torn & Glasser "Mixed Nuts Fancy, No Peanuts" due to undeclared Peanuts (August 26, 2010).

Recently Posted Warning Letters
FDA warned Specialty Brands of America that a review of its label for “Bear Creek Country Kitchens Navy Bean Soup Mix” found that the product misbranded because it bears an impermissible nutrient content claim, specifically the nutrient content claim is not accompanied by the required sodium disclosure.


FDA warned Dr. Pepper Snapple Group that based on a review of its product label and web site, the green tea ginger ale product is misbranded due to unauthorized claims and violations of FDA’s fortification policy. FDA also warned David’s Cookies that David’s Chocolate Marble Truffle Cake product is misbranded due to unauthorized nutrient content claims.

FDA warned Unilever United States, Inc, that its products contained improper labeling (which included content on the company web sites, incorporated into the product label by reference) due to unauthorized nutrient content claims. FDA warned that Lipton Green Tea 100% Naturally Decaffeinated was marketed for conditions that cause the product to be a drug.

FDA warned Quong Hop & Co that its products are adulterated due to being prepared, packed, or held under insanitary conditions and its Raquel's Hummus & Dip Spicy Hummus product is misbranded due to a failure to label the common or usual name of each ingredient and that the nutrition facts panel is not properly formatted.
New Regulatory Notices

FDA Proposes Information Collection on Additive, GRAS Affirmation Petitions
In the August 30, 2010 Federal Register, FDA announced that a proposed collection of information has been submitted to the Office of Management and Budget concerning (1) the submission of food additive, color additive (including labeling), and Generally Recognized as Safe (GRAS) affirmation petitions; and (2) the submission of information to a master file in support of petitions; and (3) the electronic submission using FDA form 3503. Comments must be received by September 29, 2010.

FSIS Policy Updates
FSIS recently published the following revised export requirements and plant lists:
- Republic of Korea (Sep 7, 2010)
- Mexico (Sep 7, 2010)
- Mexico Plant List (Aug 26, 2010)
- Russia Plant List, Pork (Aug 26, 2010)

FSIS recently published the following Notices:
- 46-10 Manufacture of Animal Food or Uninspected Articles at Official Establishments
- 47-10 Certification Statements on Egg Products Inspection and Grading Certificates, FSIS Form PY-200
- 48-10 Ensuring Sample Integrity when Submitting Residue Samples to the Laboratory for Residue Testing

Regulatory Notices with Open Comment Periods

FDA Seeks Comments on Information Collection for CGMPs for Dietary Supplements
In the July 14, 2010 Federal Register, 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 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:

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 August 2010; and


Links to the guidance documents and other helpful information are available on FDA’s web page on New Menu and Vending Machines Labeling Requirements. 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 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.

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.
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
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.

National Advisory Committee on Meat and Poultry Inspection to Hold Public Meeting
The National Advisory Committee on Meat and Poultry Inspection (NACMPI) will hold a public meeting on September 29 and 30. The committee advises the Secretary of Agriculture on matters affecting federal and state inspection program activities. The meetings will be held in Washington, D.C. More information will be made available at the Meetings and Events page on FSIS’ website at www.fsis.usda.gov/News_&_Events/Metings_&_Events/index.asp. For further information about the public meeting, contact Josh Stull at (202) 720-9113 or e-mail josh.stull@fsis.usda.gov.

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](http://www.bryancave.com) on the FDA Practice Bulletins web page. If you have any questions regarding any of these issues, please contact:

- **Mark Mansour**
  - Partner  
  - mark.mansour@bryancave.com  
  - 1 202 508 6019  
  - Washington

- **Megan A. Gajewski**
  - Associate  
  - megan.gajewski@bryancave.com  
  - 1 202 508 6302  
  - Washington

- **Patrice M. Hayden**
  - Associate  
  - pmhayden@bryancave.com  
  - 1 202 508 6147  
  - Washington

- **Emily K. Strunk**
  - Associate  
  - emily.strunk@bryancave.com  
  - 1 202 508 6360  
  - Washington

This bulletin is published for the clients and friends of Bryan Cave LLP. To stop this bulletin, please reply to this email. To stop this bulletin and all future commercial e-mail from Bryan Cave LLP, please reply to: [opt-out@bryancave.com](mailto:opt-out@bryancave.com) and leave the message blank. Information contained herein is not to be considered as legal advice. Under the ethics rules of certain bar associations, this bulletin may be construed as an advertisement or solicitation.