

To: Our Clients and Friends

April 19, 2010

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



### Top News

#### Senate Once Again Delays Food Safety Vote

After much anticipation that the Senate, having finally passed health care reform, would take up the food safety bill (S.510) this week, the vote was once again postponed. Wall Street reform will be the next issue to occupy the Senate floor and is anticipated to last for two weeks. Food safety legislation expected to come up after the Senate has finished with Wall Street reform, and proponents of the legislation remain optimistic that the bill will pass before the next congressional recess. The bill has wide bipartisan support and is expected to pass without controversy.

#### Small Farmers Concerned That Food Safety Bill Will Jeopardize Their Livelihood

As food safety legislation draws nearer to consideration in the Senate, small farmers are concerned that, if passed, the legislation will require FDA to implement regulations that are too burdensome or expensive for small farmers to keep up with. Such regulations include user fees, and increased inspections. An amendment by Senator Jon Tester (D-MT) would exempt small-scale producers from the requirements of the bill.

#### USDA OIG Finds Tainted Beef Reaching Consumers

USDA's OIG, in an [audit of the agency's Food Safety Inspection Service \(FSIS\) National Residue Program for Cattle](#), criticizes USDA, FDA, and EPA for not establishing thresholds for many dangerous substances, resulting in meat with these hazardous substances being distributed in the food supply. Additionally, the report found that FSIS does not recall meat that it has tested and found to contain excessive presence of veterinary drugs. [USA Today](#) reported on the issue in detail.

#### NAD Says "Complete" Pre-Natal Vitamin Claim Is not Completely Substantiated

Nature Made, which had been advertising its Prenatal Multi + DHA Liquid Softgels as the only complete single-dose prenatal vitamin, will stop using the "complete" claim after the National Advertising Division (NAD) decided that the firm cannot substantiate the bioavailability of folic acid in the vitamin. Although Pharmavite insists that its product exceeds USP standards for folic acid absorption, it is complying with the NAD decision while it conducts additional conformity testing. NAD stressed the importance of the folic acid needs of expectant mothers to prevent birth defects. The NAD decision resulted from a challenge by Pharmavite's competitor, Perrigo.

## UK Survey Says Docs Not Very Knowledgeable on Supplements

A survey of doctors in the United Kingdom found that most doctors thought that, in general the members of their profession were poorly educated on the use of supplements and many rated their own knowledge as much poorer than average. Stakeholders and experts in the dietary supplement industry say that the issue is problematic for several reasons including not offering patients a full-range of care and not being informed about potential drug-supplement interactions.

## FDA Publishes Guidance on the Egg Rule

On April 13, 2010, FDA published [guidance for small egg producers](#) to help them comply with a 2009 federal egg safety regulation designed to prevent Salmonella Enteritidis in shell eggs during production, transportation, and storage.

[Guidance for Industry: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage: Small Entity Compliance Guide](#) sets forth, in plain language, the legal requirements of the 2009 egg safety regulation, which became effective on September 8, 2009.

## FSIS Prepares for Food Defense Plan Survey

This summer, USDA's Food Safety and Inspection Service (FSIS) will repeat its [Food Defense Plan](#) Survey to determine how many FSIS-regulated slaughter and processing establishments have voluntarily adopted a functional food defense plan. Results from the December 2009 survey indicated that approximately 62 percent of all plants have adopted plans. In November 2009, FSIS issued general guidance to assist establishments and encourage voluntary adoption of sound and functional defense plans. This general plan will be mailed next month to establishments that did not have one when surveyed last year.

## CDC Reports Success in Fighting E. coli Infections

[The rate of a severe form of Escherichia coli diarrhea significantly decreased in 2009](#), reaching the lowest level since 2004 and meeting the national 2010 Health People target in 2009, according to a report released by the Centers for Disease Control and Prevention on April 15, 2010.

## USDA Under Secretary Testifies on Healthful Foods

Kevin Concannon, Under Secretary Food, Nutrition and Consumer Services [testified on healthful foods in the nutrition assistance program](#) before the House Committee on Agriculture Subcommittee on Department Operations, Oversight, Nutrition and Forestry. USDA oversees 15 nutrition assistance programs, and improving access to food, specifically healthy and nutritious food, is central to USDA's food and nutrition efforts.

## FDA Updates Import Refusals Related to Cosmetics

FDA recently updated its web page for [Import Refusals Related to Cosmetics](#) to include reports for January, February, and March 2010. The reports list the refusal actions by FDA for the given month.

## Briefly Noted

[USDA releases podcast on irradiation of food.](#)

[FoodSafety.gov posts Q & A about the HVP recall.](#)

[Monsanto seeks approval of GM corn and soy in Australia.](#)

[National Academy of Sciences releases study, concludes that GM seeks benefit many farmers.](#)

[Produce in poorer neighborhoods are more likely to be laden with bacteria, mold, and yeast.](#)

[Washington Post discusses challenges for organic food market with USDA Deputy Secretary Kathleen Merrigan.](#)

[The debate over raw milk rages on.](#)

## Recent Recalls

[Certain Purina Mills horse feed and poultry feed products](#) due to potential inclusion of metal fragments (April 19, 2010).

[Westlake Food Corporation various fully cooked assorted meat products](#) due to undeclared wheat (April 17, 2010).

[Green Land Nut Tree Health Mix](#) due to undeclared sulfites (April 16, 2010).

[StarKist Co. SeaSations frozen white whole fish fillet products](#) due to undeclared wheat (April 15, 2010).

[MY-A & Co. Ground Black Pepper Double Golden Fish](#) due to possible salmonella contamination (April 14, 2010).

[Response Products Cetyl M for Dogs](#) due to potential salmonella contamination from contaminated HVP (April 12, 2010).

[Atlas Operations dietary supplements for sexual enhancement](#) due to presence of Sulfoaildenafil (drug) (April 12, 2010).

[H-E-B French Onion Dip](#) due to possible salmonella contamination (April 9, 2010).

## Recently Posted Warning Letters

A warning letter to [Wisconsin Brother's Bakery](#) stated that a review of product labels and other evidence revealed that the products are misbranded because the firm's web site claimed that the products contained butter and blanched almonds when they did not and also because certain products failed to declare major food allergens, did not list all ingredients, did not adequately list sub-ingredients, did not properly declare serving size, and did not properly format the nutrition facts panel. Also of note, the warning letter declared that the firm's web site was labeling under the Federal Food, Drug, and Cosmetic Act because it appears on the product labels.

A warning letter to [Cut Fruit Express](#) stated that inspectors documented serious violations of the juice Hazard Analysis and Critical Control Point (HACCP) regulations and Current Good Manufacturing Practice (CGMP) regulations for food causing the firm's 100% juices (orange, grapefruit) to be misbranded and adulterated.

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## Regulatory Notices

### FDA Issues Technical Amendment to Egg Rule

On April 13, 2010, FDA issued a notice in the [Federal Register](#) that it is amending its regulations to correct the date by which producers must register their farm with FDA, reflect a change in the address and telephone number for requesting copies of Form No. 3733, and reflect a change in the address to which producers must send their CD-ROM. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations. It is effective immediately.

### 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.

## FSIS Updates

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

- [Taiwan](#) (Apr 16, 2010)
- [China](#) (Apr 15, 2010)

## FSIS recently published two Notices:

- [FSIS Notice 21-10](#), Submission of FSIS Form 10,240-1, Production Information on Post-Lethality Exposed Ready-To-Eat (RTE) Products.
- [FSIS Direction 7120.1 Revision 2](#), Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products.

## FDA Amends Color Additive Regulations

On [March 26, 2010](#), FDA amended the [color additive regulations](#) to increase the permitted use level of bismuth citrate as a color additive in cosmetics intended for coloring hair on the scalp. This action is in response to a petition filed by Combe, Inc. and effective April 27, 2010. Electronic or written objections and requests for a hearing may must be submitted by **April 26, 2010**.

## 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 control plans, that is, its 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 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 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**.

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## ***Upcoming Meetings***

### **FDA is Seeking Consumer Representatives on Advisory Committees**

FDA is holding a public meeting on **April 30, 2010** for individuals and groups interested in nominating or serving as consumer representatives to FDA's advisory committees and panels. Additional information about the meeting and the criteria for selecting consumer representatives is available in the [meeting announcement](#) on FDA's web site.

### **Let's Talk: Food Safety Assessments (FSAs) and Recalls**

On May 4, FSIS will host a Web seminar, *Lessons Learned From FSAs and Recalls During the Fiscal Year 2010 Second Quarter*. This seminar will discuss issues concerning for-cause FSAs and class 1 recalls related to *Listeria*, *E. coli* and *Salmonella*. The meeting will be held on May 4 from 11:30 a.m. to 12:30 p.m. (ET). To participate, call (800) 857-5750, and use the passcode FSA. To join online, go to [www.mymeetings.com/nc/join.php?i=PW7154220&p=FSA&t=c](http://www.mymeetings.com/nc/join.php?i=PW7154220&p=FSA&t=c). For additional information, contact Denise Gallman at (301) 504-3346 or [netmeetingseminars@fsis.usda.gov](mailto:netmeetingseminars@fsis.usda.gov).

### **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 will be limited to 30 individuals. USDA has created a [web page with more information where participants can register](#). Additional seminars will be held in August and September.

## 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. All interested persons, regardless of whether they can attend, may submit written comments to the docket, which will remain open for 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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