To: Our Clients and Friends  

October 30, 2009  

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin  

Top News  

FDA Commissioner Hamburg Endorses Food Safety Bill  

Several mainstream news outlets reported on FDA Commissioner Margaret Hamburg’s Testimony at the Senate Health Education Labor and Pensions Committee Hearing last Thursday, October 22, 2009. The Los Angeles Times, New York Times, and Wall Street Journal all generally reported that Dr. Hamburg strongly supports the legislation but is concerned that it does not go far enough. She also stressed that adequate funding will be necessary to enable the FDA to carry out its increased duties under the bill. On a related note, Progressive Grocer reports that affluent shoppers are willing to pay more for food they believe is safer or healthier.  

IOM Launches FOP Food Label Study  

Last week we reported that the FDA issued an industry guidance in the form of a Letter Regarding Point of Purchase for Food Labeling, with a heavy emphasis on front of package (FOP) labeling. Alongside this effort, Inside Health Policy (subscription required) reports that the Institute of Medicine is launching it’s Congressionally funded FOP food label study. The study will “examine and provide recommendations regarding front-of-package nutrition symbols,” according to its mandate from the House Appropriations Committee. “These should include, but not be limited to, a review of systems being used by manufacturers, supermarkets, health organizations, and governments in the United States and abroad and the overall merits of front-label nutrition icons, the advantages and disadvantages of various approaches, and the potential benefits of a single, standardized front-label food guidance system regulated by the Food and Drug Administration.” In the meantime, U.S. manufacturers are reportedly moving away from the Smart Choices program, which uses FOP labeling in the form of a green checkmark to indicate a product is a smart choice. The program has recently come under investigation by the Connecticut Attorney General and was suspended on October 23, 2009.
FDA Continues Food Safety Strategies at National and State Levels

This week, InsideHealthPolicy.com (subscription required) reported that it had obtained an internal FDA memo laid out the FDA’s five-year strategic vision for an integrated national food safety system, but said that such a system will require additional staff and new legislative authorities. In a second article, InsideHealthPolicy.com (subscription required) also reported that the FDA is holding compliance strategy meetings with its state counterparts. The meetings have focused on how to best deal with egregious violations at food facilities.

President Obama Signs Agricultural Appropriations Bill with Increased Funding for Food Safety and other Food Programs

Last week, President Obama signed the FY 2010 Agricultural Appropriations bill (Public Law No. 111-80), which includes $2.36 billion for food and medical device safety. This amount was more than $300 million greater than the previous year and $7 million more than President Obama had requested. Supermarket News reports that $100 billion, about 80 percent of the appropriations, will be invested in food stamps and school nutrition programs. The bill also included significant funding for the dairy industry.

Sharfstein Outlines Priorities at Council for Responsible Nutrition’s Conference

FDA Principal Deputy Commissioner Joshua Sharfstein addressed the Council for Responsible Nutrition (CRN) at their annual dietary supplement conference in California last week. Dr. Sharfstein said that his top priority is creating better policies for new ingredient premarket notification in order for FDA to adequately oversee new ingredient introductions. He is particularly concerned with spiking and adulteration. However, Sharfstein also noted that the FDA and dietary supplement industry must work together to enforce existing laws, ensure GMP and quality control, particularly over products imported from abroad, and reporting post-market problems with products that are adulterated, deceptive, or pose a risk. The president and CEO of CRN also stressed the need for the dietary supplement industry to work with the FDA, but within the existing legislative framework. On a related note, CRN released the results of its annual survey on dietary supplement use, which found a slight increase in the percentage of Americans who are taking dietary supplements as compared to last year.

New FDA Policy Will Provide Companies Closure on Warning Letters

The FDA issues warning letters when the agency discovers that a company has violated FDA regulations. In a new policy, the FDA may issue a Warning Letter close-out letter (“close-out letter”) once the Agency has completed an evaluation of corrective actions undertaken by a firm in response to a Warning Letter. A close-out letter may issue when, based on FDA’s evaluation, the firm has taken corrective action to address the violations contained in the Warning Letter.

FDA Gives GM Soybean Oil GRAS Status

The FDA announced that a soybean oil developed by Monsanto and Solae was “generally recognized as safe,” or GRAS.

NIH Allocates $30 Million to Study Safety of BPA

The National Institutes of Health will invest $30 million to study the effects of exposure to low-doses of Bisphenol-A (BPA) on behavior, obesity, and other medical conditions, including cancers, USA Today reports. Almost half the funds will come from the economic stimulus bill. The FDA is scheduled to issue its own report on the safety of BPA in November.
USDA Awards $19 Million In Organic Research, Education, And Extension Grants

Agriculture Deputy Secretary Kathleen Merrigan announced on October 30, 2009, that the USDA would grant more than $19 million to universities across the country to solve critical organic agriculture issues through the integration of research, education, and extension projects.

Consumers Weigh In On Most Important Claims

In a recent survey of the health claims most important to consumers (who were mostly affluent and educated), respondents indicated that while food safety claims were the most important, claims of “organic” and “free-range” were slipping in importance. The top three claims were “low-mercury seafood,” “no pesticides,” and “no artificial hormones.”

China Agrees to Reopen Its Market to U.S. Pork and Live Swine

On October 29, 2009, China agreed to reopen its markets to U.S. pork and live swine. The USDA also issued a press release providing additional background on the issue.

CDC Issues First-Ever State Indicator Report on Fruits and Vegetables

The Centers for Disease Control and Prevention issued its first-ever State Indicator Report on Fruits and Vegetables, which provides information on how many fruits and vegetables people are eating and highlights key areas within communities and schools that can be improved to increase access, availability, and affordability of fruits and vegetables.

USDA Reviews Administration’s Priorities for Child Nutrition Act Reauthorization

Last week, Agriculture Secretary Tom Vilsack previewed the Obama Administration's legislative priorities for reauthorization of the Child Nutrition Act that is currently being considered by Congress. This legislation, renewed every five years, provides the outline for the National School Lunch and Breakfast Programs which serve more than 31 million children in more than 100,000 schools across the country.

Recent Recalls

Mr. Rios Corn Products flour tortillas due to the potential presence of undeclared whey (October 28, 2009).

Pinnacle Foods Group canned chili beans due to inaccurate “gluten free” labeling and presence of undeclared wheat (October 28, 2009).

Pop’s Bakery flour tortillas due to the potential presence of undeclared whey (October 27, 2009).

Dove Caramel Pecan Perfection ice cream due to the potential presence of undeclared peanuts (October 26, 2009).

San Link Vacuum Pack Dried Lesh (fish) and Vacuum Pack Dried Krasnoperka (fish) due to products being uneviscerated (October 26, 2009).

South Shore Meats fresh ground beef patties due to the possible contamination with E.coli (October 26, 2009).

Limited number of tubs of Breyers All Natural Ice Cream due to product being mislabeled as two different products and undeclared presence of wheat (October 22, 2009).
Regulatory Notices

FDA Requests Comments on Recordkeeping Requirements For Food and Cosmetics Using Cattle and Microbiological Testing for Bottled Water

On October 23, 2009, the FDA issued a request for comments with regard to the recordkeeping and reporting requirements for human food and cosmetics manufactured from, processed with, or otherwise containing, material from cattle. The notice is available at http://edocket.access.gpo.gov/2009/pdf/E9-25537.pdf.

On October 28, 2009, the FDA issued a request for comments with regard to the recordkeeping requirements for microbiological testing and corrective measures for bottled water. The notice is available at http://edocket.access.gpo.gov/2009/pdf/E9-25927.pdf.

USDA FSIS Requests Comments on Information Collection

USDA FSIS is planning to request a revision of an information collection addressing paperwork requirements related to the collection of information for the exportation, transportation, and importation of meat and poultry products because this information collection is scheduled to expire in January 2010, and because the Agency now has more accurate data regarding the forms used to export and import product. The notice is available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0018.htm.

Upcoming Meetings

FSIS Meeting on Cooperative Inspection Programs: Interstate Shipment of Meat and Poultry Products

On November 5, 2009, the Food Safety and Inspection Service (FSIS) will hold the second of two public meetings on recently published proposed regulations to implement a new voluntary cooperative program under which State-inspected establishments with 25 or fewer employees will be eligible to ship meat and poultry products in interstate commerce (74 FR 47648, September 16, 2009). The meetings will be conducted by teleconference. Pre-registration is required. To pre-register, access the FSIS Web site, at http://www.fsis.usda.gov/News/Meetings & Events/.

FSIS Web Outreach Seminar on Selecting Good Manufacturing Practices

The final session of the FSIS web outreach seminars to promote uniform understanding of FSIS regulations for plant owners and operators, especially those of small and very small plants, is scheduled for November 5, 2009. The topic is selecting good manufacturing practices and sanitation performance standards necessary to support a small plant’s food safety system. To register, go to http://www.fsis.usda.gov/News & Events/Regulatory_Web_Seminars/index.asp.
More Information

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