Top Stories

FDA Finalizes Expanded Records Access Rule and Issues Guidance
On April 4, 2014 FDA finalized an interim final rule and issued two guidance documents outlining how the agency will implement its expanded authority to access records under the Food Safety Modernization Act ("FSMA"). Before FSMA, FDA's records access authority was limited to records for food articles that FDA reasonably believed to be adulterated and presented a threat of serious adverse health consequences or death to humans or animals. Pursuant to FSMA, and the final rule, FDA may now access records for food articles that the agency believes may be affected in a similar manner to a suspect food, even if there is no evidence that the specific food article is adulterated or presents a threat. The final rule finalizes without changes an interim final rule amending FDA regulations to reflect FDA's enhanced authority to review records. To help industry understand and comply with the final rule, FDA also released two Guidances for industry, including a Small Entity Compliance Guide. The second guidance document is available here. For additional information, please click here to read the *Jones Day Alert*.

FDA Finalizes Board Member Conflict of Interest Policies
On March 31, FDA finalized policies for the public disclosure of financial ties of advisory board members whose votes may prove critical to the approval of new drugs and medical devices. The goal of the policies is to increase the transparency, consistency, and clarity of the advisory committee process. The guidance includes two forms that FDA will use to screen members and release information about business relationships that could compromise board member impartiality. FDA made clear, however, that some details will not be disclosed if they are exempt from the Freedom of Information Act (FOIA).

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Resources

- Jones Day's Health Care Practice
- Jones Day's Life Sciences Practice

Meat Groups Get Another Chance To Delay Enforcement of COOL Rules
On April 4, a Federal Appeals Court threw out the District Court's March 28 denial of meat producers' request to delay enforcement of USDA's new country-of-original labeling (COOL) requirements. The Appeals Court ordered that the case be reheard en banc on May 19, 2014. USDA's final COOL rule, published in May 2013, requires producers to specify the country or countries where an animal was born, raised and slaughtered and prohibits industry from mixing muscle cuts from different countries under a generic label. Meatpackers, led by the American Meat Institute, argued that the rule forces

them to segregate animals and raises costs. But other American producers, such as ranchers, favor the labeling because it allows consumers to identify American-produced meat. The rule strengthens the 2009 COOL requirements, which merely required a simple label declaring "product of [country or countries]" and permitted commingling of meat from different countries.

FDA Issues Revised Draft Guidance on Prior Notice of Imported Foods
On March 28, FDA released a draft guidance *Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3).* The latest edition addresses questions FDA received since the second edition's publication in 2004 and is intended to assist food industry in complying with FSMA's prior notice requirements for imported foods. ***Comments due May 30.***

Makers of Caffeinated Alcoholic Beverages Settle with State AGs
The maker of Four Loko will no longer sell alcoholic beverages that contain caffeine, among other concessions agreed to by Phusion Projects as part of a settlement with 20 states and San Francisco to resolve allegations that it improperly marketed flavored malt beverages to young people and encouraged alcohol abuse. As part of the agreement, the company will pay $400,000 to each of the involved states and reform its advertising practices to help prevent those under 21 from buying alcoholic products. FDA banned caffeine in alcoholic beverages in 2010 and continues to take interest in regulating caffeine as a food additive.

Other News
FDA Reports All But One Animal Drug Sponsor Committed To Antibiotic Policy

GMA Petitions FDA To Issue A Regulation Authorizing Statements Such As "Natural" On GM Foods

Hamburg Testifies To House Subcommittee That Requiring Labels For GM Foods Is Unnecessary

EFSA Issues Scientific Opinion on Salmonella and Norovirus Risks in Leafy Greens

FSIS Responds to Claims that Inspector Shortage Will Mean More Recalls

Vermont GMO Labeling Bill Makes Headway

Two Studies Link Cancer and Heart Disease To Low Vitamin D Levels.

Regulatory Updates

FDA Finalizes Rule and Guidances On Record Access Requirements
In the April 4 *Federal Register*, FDA released two Guidances and finalized the rule implementing its expanded authority to access records of food manufacturers under the Food Safety Modernization Act ("FSMA"). The final rule adopts the interim rule without any changes. One of the Guidances addresses the entire industry, the other specifically targets smaller firms.

FDA Announces Availability of Draft Guidance for Industry on Imported Food
In the March 31 *Federal Register*, FDA announced a draft guidance entitled *Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3).* The draft guidance addresses questions received since the publication of the second edition of the guidance in May 2004 and includes information related to FSMA's requirement that firms report on a prior notice the name of any country which has refused entry to products now seeking import into the United States. ***Comments due May 30.***

FDA Issues Guidance on Financial Interests
In the March 31 *Federal Register*, FDA announced a guidance document entitled *Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers*. The guidance replaces a 2012 version and provides forms to facilitate disclosures and potential waivers of conflicts of interest for advisory committee members.

FDA Amends Animal Drug Regulations to Reflect Recent NADA and ANADA Approvals
In the April 1 *Federal Register*, FDA amended its animal drug regulations to reflect approval of actions

for six new animal drug applications during January and February 2014. The regulations were additionally amended to more accurately reflect previously approved revisions to food safety warnings for several other drugs, and two changes in sponsorship. The amendments also reflect two changes in sponsorship.

FDA Announces Opportunity to Comment on Turkey Food Additive Petition
In the March 26 *Federal Register*, the FDA called for comments to a food additive petition by DSM Nutritional Products proposing the safe use of 25-hydroxyvitamin D3 in feed for turkeys. ***Comments due April 25.***

USDA's APHIS Issues Four New Quarantine Treatment Schedules for Food
In the March 28 *Federal Register*, the Animal and Plant Health Inspection Service (APHIS) advised the public that it has added several treatment schedules for various plant commodities to the Plant Protection and Quarantine Treatment Manual. ***Comments due May 27.***

USDA's APHIS Announces Final Rule on Importation of Potatoes from Mexico
In the March 26 *Federal Register*, APHIS announced it had amended the regulations concerning the importation of fruits and vegetables to allow the importation of fresh potatoes (*Solanum tuberosum L.*) from Mexico into the United States. As a condition of entry, the potatoes must be produced in accordance with a systems approach employing a combination of mitigation measures to prevent the introduction and dissemination of plant pests into the United States.

Korea Eligible for Exporting Poultry to the United States
In the March 26 *Federal Register*, USDA's Food Safety Inspection Service (FSIS) amended the Federal poultry products inspection regulations to add the Republic of Korea (Korea) to the list of countries eligible to export poultry products to the United States. FSIS has reviewed Korea's poultry laws, regulations, and inspection system, as implemented, and has determined that they are equivalent to the Poultry Products Inspection Act (PPIA), the regulations implementing this statute, and the U.S. food safety system for poultry.

USDA announced the opportunity to comment on the following proposed information collections:
• Specified Risk Materials under Federal Meat Inspection Act *(comments due April 28).*
• Swine Health Protection *(comments due April 28).*
• Extension for Specified Commodities Imported Into the United States Exempt from Import Requirement. *(comments due May 30).*

FDA announced the opportunity to comment on the following proposed information collections:
• Electronic Signatures for FDA Submissions *(comments due May 27).*
• Current Good Manufacturing Practice Regulations for Medicated Feeds *(comments due June 6).*
• Current Good Manufacturing Practice Regulations for Type A Medicated Articles *(comments due June 6).*
• Index of Legally Marketed Unapproved New Animal Drugs for Minor Species *(comments due June 6).*

USDA announced that OMB has approved its proposed information collection for:
• Evaluation of the Pilot Project for Canned, Frozen, or Dried Fruits and Vegetables in the Fresh Fruit and Vegetable Program (FFVP) *(comments due May 27).*

Other USDA Announcements:
National Watermelon Promotion Board Amended Membership Requirements
Proposed Increased Assessment for California Desert Grapes ***Comments due April 15.***

Upcoming Meetings, Workshops, and Conferences

The annual Food Safety Summit will host four certification programs in HACCP, Seafood HACCP, Food Fraud, and ServSafe in addition to a variety of speakers and exhibitors. **April 7–10** in Baltimore, MD.

USDA and EPA are sponsoring a public meeting on **April 10, 2014** in Arlington, VA to provide information and receive public comments for the 46th Session of the Codex Committee on Pesticide Residues (CCPR), which will take place in China in May.

The National Organic Standards Board will hold its annual meeting on **April 29–May 2** in San Antonio, TX. ***Written comments and signup for oral public comments due April 8, 2014.***

The International Association for Food Protection will host its Annual Meeting on **August 3-6** in Indianapolis, IN. The attendees will receive information on current and emerging food safety issues, the latest science, innovative solutions to new and recurring problems, and the opportunity to network with thousands of other food safety professional.

Enforcement Updates

Recent Product Recalls

Recent food recalls were for undeclared allergens, primarily milk, eggs, fish, and nuts, in prepared foods. One dietary supplement was recalled for containing unapproved new drugs or undeclared drugs. Other recalls were for a variety bacterial contaminations.

Recent USDA recalls included two separate chicken products that were misbranded and contained undeclared allergens. Another chicken product was recalled for possible foreign matter contamination. FSIS also issued a public health alert for processed egg products unfit for human consumption.

For a complete list of product recalls, click here for FDA-regulated products, and here for USDA-regulated products.

Recent Warning Letters

Several recently posted FDA warning letters addressed insanitary manufacturing conditions and CGMP and HACCP violations, including Seafood HACCP violations at three seafood processing facilities and CGMP violations at a bakery. One aircraft servicing area, also a watering point, was cited for not having the proper design for preventing drinking and culinary water contamination and because the facility's toilets were not appropriately maintained. A shell egg production facility was warned because it violated the Shell Egg regulations in failing to follow its *Salmonella* prevention plan. FDA also found illegal drug residues due to extralabel use of medicated feed at three different facilities.

Click here for FDA's Warning Letters Home page (scroll down for listing of recently posted Warning Letters).