Top Stories

FDA Doesn't Have to Ban Antibiotics in Healthy Livestock, Rules Federal Court
Last week, a divided federal appeals court ruled that FDA cannot be forced to ban antibiotics in food-producing healthy livestock. The decision comes amid concerns that antibiotics are becoming less effective for treating humans due to increasing antibiotic resistance resulting from widespread use of antibiotics in food-producing animals, a problem that was discussed in a report issued last year by the Centers for Disease Control and Prevention. In 2011, four consumer advocacy groups filed suit to force FDA to ban the routine use of antibiotics in healthy animals, arguing that FDA should have held hearings to review scientific evidence and unfairly denied a pair of citizen petitions calling for hearings. The recent 2-to-1 decision held otherwise, giving FDA discretion to withdraw approval of animal drugs, hold hearings when officials have scientific concerns, and choose the most cost-effective approach to addressing problems.

Parallel to this lawsuit, however, FDA has been developing an antibiotic resistance strategy calling for animal drug makers to voluntarily revise the FDA-approved indications for use for certain products to reduce the use of antibiotics in healthy livestock. This strategy has triggered mixed reactions because the pharmaceutical industry is not required to cooperate, although FDA recently announced it had full cooperation of the major manufacturers. The court's decision effectively permits FDA to continue pursuing this strategy.

China Still Struggling to Improve Food Safety
China continues to struggle in its efforts to improve food safety regulation and oversight, in the wake of a succession of food safety problems. A recent news report revealed hidden-camera footage showing Shanghai processing plant workers using meat that was expired and meat that had been dropped on the floor to make burger patties and chicken products for fast food restaurants. "Although China is by outward appearance an incredibly modern and vibrant society, it just doesn't have a long history of regulatory control, of checks and balances, where somebody is making the decision, 'If the meat falls on the floor, should I put it back in?'" said a Seattle-based consumer lawyer in a recent

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Resources

- *Food, Dietary Supplement & Cosmetics Regulatory Update* Printable Version
- Jones Day's FDA Regulatory & Compliance Counseling Practice
- Jones Day's Health Care Practice

- Jones Day's Life Sciences Practice

New York Times article. Other observers cite the lack of a vigorous civil torts system in China as a contributing reason for the continued food safety problems, arguing that such high-stakes cases influence companies' behavior. In the same article, a professor of food microbiology at Rutgers University recently described China as "kind of like the U.S. in the time of Upton Sinclair and 'The Jungle,'" referring to the 1906 novel that described unsanitary conditions in the meatpacking industry. "There is tremendous desire by the Chinese to get it right, but they have a long way to go."

Health Canada Proposes Nutrition Labeling Changes that Echo Recent FDA Proposals
On July 14, 2014, Health Canada, the Canadian food regulatory authority, announced key changes to the nutrition information on food labels in response to consumer demands and the latest scientific information. The agency says that revised labels will make it easier for Canadians to read and understand food labels and make healthy food choices. According to the Canadian Minister of Health, "Nutrition [labeling] is an important public health tool that can help Canadians make healthier food choices to improve their health and help reduce their risk of obesity and chronic diseases." Health Canada's proposed nutrition labeling changes echo recent FDA proposals, which also propose updated serving sizes and a new design for nutrition facts labels with the goal of influencing consumers' eating habits. Health Canada's Food Directorate discussed the changes in five associated technical consultation documents covering topics such as serving sizes, daily values, core nutrients, and nutrition formats for food labels. The Health Canada documents are open for public comment until September 12, 2014; the comment period for the FDA proposed changes closed on August 1, 2014.

Consumer Groups Back Vermont Biotech Labeling Legislation
The Center for Food Safety ("CFS") and Vermont Public Interest Research Group (VPIRG) filed a motion to join the lawsuit brought by the Grocery Manufacturers Association challenging the new Vermont law requiring the labeling of foods derived from biotechnology. CFS and VPIRG argue that they have a right to be included in the lawsuit because they have strong interests in the action and may be impaired by its outcome, and the state of Vermont may not adequately represent their interests. In an interesting twist, Ben & Jerry's recently expressed its support of the Vermont law, despite its parent company's opposition to transgenic labeling laws. The biotech food labeling controversy continues across the country, with more than 12 states currently considering legislation.

Other News
USDA Proposes Allowing Pork Imports From More Mexican Regions

FDA Announces FY 2015 User Fees for Domestic and Foreign Facility Reinspections, Failure to Comply with Recall Orders, and Certain Importer Reinspections

FDA Signs Statement of Intent with Mexican Counterparts to Strengthen Produce Safety

FDA Updates CFSAN Constituents and Consumers on New Gluten-Free Labeling Rule

Regulatory Updates

FDA Announces FY 2015 User Fees for Food Facility Reinspections and Recalls
In the August 1, 2014, *Federal Register*, FDA announced fee rates for fiscal year 2015 for certain domestic and foreign facility reinspections, failures to comply with recall orders, and importer reinspections. Authorized by the Food Safety Modernization Act, these fees are effective October 1, 2014, through September 30, 2015.

FDA Announces FY 2015 User Fees for Animal Drugs and Animal Generic Drugs
In the August 1, 2014, *Federal Register*, FDA issued notices regarding the rates and payment procedures for fiscal year 2015 for animal drug user fees and animal generic drug user fees. Pursuant to the Animal Drug User Fee Amendments of 2013 to the Food, Drug, and Cosmetic Act ("FDCA"), FDA collects user fees for certain animal drug applications and supplements, animal drug products, establishments where such products are made, and application and submission sponsors.

FDA Issues Draft Guidance on Cell-Based Products for Animal Use
In the August 1, 2014, *Federal Register*, FDA issued a draft guidance for industry, *Cell-Based Products for Animal Use*, describing FDA's Center for Veterinary Medicine's current thinking on cell-based products for animal use that meet the definition of a new animal drug. The guidance specifies that new animal drug products intended for use in food-producing animals have the potential to affect edible tissues entering the human food supply. As with any investigational use of a new animal drug in food-producing animals, edible products of investigational animals are not to be used for food unless authorization has been granted by FDA. ***Comments are due September 30, 2014***.

USDA Issues Final Rule on Federal Procurement Guidelines for Biobased Products
In the August 1, 2014, *Federal Register*, USDA issued a final rule amending regulations concerning Guidelines for Designating Biobased Products for Federal Procurement, or the requirements regarding the Farm Security and Rural Investment Act ("FSRIA") procurement programs. This final rule updates the Guidelines to account for legislative amendments to FSRIA enacted in 2008. An additional rulemaking will be initiated to further amend the Guidelines to address the provisions of the recently signed Agricultural Act of 2014.

FDA Amends Animal Drug Rules to Reflect Withdrawal and Approvals
In the July 31, 2014, *Federal Register*, FDA issued a final rule amending its animal drug regulations to reflect approval actions and to remove a combination drug medicated feed that is no longer codified. The changes reflect five applications approved in June 2014.

USDA Issues Final Rule to Allow Import of Fresh Blueberries from Morocco
In the July 30, 2014, *Federal Register*, USDA issued a final rule allowing the importation of fresh blueberries from Morocco into the continental United States. As a condition of entry, the blueberries must be produced under a systems approach employing a combination of mitigation measures for two quarantine pests (Ceratitis capitata and Monilinia fructigena) and must be inspected prior to exportation and found free of these pests. Imports are limited to commercial consignments only and are subject to pesticide and sanitary certification requirements.

USDA Revises Delegations of Authority Within Agency
In the July 30, 2014, *Federal Register*, USDA issued a file rule revising the delegations of authority from the Secretary of Agriculture and general officers of USDA to reflect changes and additions to the delegations required by the Agricultural Act of 2014.

USDA Proposes Rule Restrictions on the Importation of Fresh Pork and Pork Products From a Region in Mexico
In the July 29, 2014, *Federal Register*, USDA issued a proposed rule to define a low-risk classical swine fever region in Mexico and allow for the importation of fresh pork and pork products from that region under certain conditions. Under the proposed rule, such pork and pork products would have to be derived from swine raised on farms meeting stringent sanitary and biosecurity requirements. Slaughter establishments would also be subject to periodic inspection and evaluation by the Animal and Plant Health Inspection Service. ***Comments are due September 29, 2014***.

USDA Fixes Typographical Errors in Previously Published Notices
USDA recently fixed typographical errors in two notices published previously this year. In the July 28, 2014, *Federal Register*, USDA corrected a July 16, 2014 notice titled "National School Lunch, Special Milk, and School Breakfast Programs: National Average Payments/Maximum Reimbursement Rates." Separately, in the July 31, 2014, *Federal Register*, USDA made a correction to a July 9, 2014 rule document (2014-16037) regarding the National Poultry Improvement Plan and Auxiliary Provisions.

FDA INFORMATION COLLECTION ACTIVITIES

FDA Announces the Opportunity to Comment on the Following Proposed Information Collections
Recordkeeping and Reporting Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing Material From Cattle (*comments due September 30, 2014*)

FDA Announces the Following Information Collections Have Been Submitted to OMB
Customer/Partner Service Surveys (*comments due to OMB August 25, 2014*)

FDA Announces the Following Information Collections Have Been Approved by OMB
Animal Generic Drug User Fee Cover Sheet

FDA Safety Communication Readership Survey

USDA INFORMATION COLLECTION ACTIVITIES

USDA Announces the Opportunity to Comment on the Following Request for Revisions to and/or Extensions of Approval of Information Collections
Servicing of Community and Direct Business Programs Loans and Grants (*comments due September 22, 2014*)

Commercial Transportation of Equines for Slaughter (*comments due September 29, 2014*)

USDA Announces the Following Information Collections Have Been Submitted to OMB
Importation of Fruits and Vegetables (*comments due to OMB August 21, 2014*)

Supplemental Nutrition Assistance Program Repayment Demand and Program Disqualification (*comments due to OMB August 21, 2014*)

Transfer of Farm Records Between Counties (*comments due to OMB August 21, 2014*)

Johne's Disease (*comments due to OMB August 25, 2014*)

Supplemental Nutrition Assistance Program—Store Applications (*comments due to OMB August 27, 2014*)

Special Supplemental Nutrition Program for Women, Infants, and Children Nutrition Education Study (*comments due to OMB August 28, 2014*)

Research Education Extension Project Online Reporting Tool (REEport) (*comments due to OMB August 28, 2014*)

General Administrative Regulations; Subpart V-Submission of Policies, Provisions of Policies, Rates of Premium, and Non-Reinsured Supplemental Policies (*comments due to OMB September 2, 2014*)

Other USDA Announcements
Funding Available for 2501 Program for Socially Disadvantaged and Veteran Farmers, Ranchers (*proposal submissions due August 25, 2014*)

Spearmint Oil Assessment Rate (*rates effective July 28, 2014*)

USDA Proposes Rule to Modify Macadamia Tree and Nut Crop Insurance Provisions (*comments due September 30, 2014*)

USDA Issues Interim Rule Approving Tests for Bovine Tuberculosis in Deer (*comments due September 29, 2014*)

USDA Proposes Rule to Allow Importation of Two Hybrids of Unshu Orange from Korea (*comments due September, 29, 2014*)

USDA–FCIC Finalizes Rule on Pear Crop Insurance Provisions

FDA Announces Petition Requesting Safe Use of Sodium Formate Additive in Swine Feed

USDA–GIPSA Proposes Revisions to U.S. Standards for Barley (*comments due September 23, 2014*)

USDA Renews Two-Year Charter for Advisory Committee on Agriculture Statistics

USDA–GIPSA Finalizes U.S. Color Grading Standard for Whole Dry Peas

Upcoming Meetings, Workshops, and Conferences

Meeting of the Codex Committee on Processed Fruits and Vegetables, **August 12, 2014**, in Washington, D.C.

Meeting of the Agricultural Air Quality Task Force, **August 20–21, 2014**, in College Station, TX, with opportunity for public comment.

FDA Food Advisory Committee, **September 29–30, 2014**, in Silver Spring, MD.

Enforcement Updates

Recent Product Recalls

Recent food recalls were primarily for reasons of microbial contamination, but two meat products, regulated by USDA, were also recalled for undeclared allergens. Multiple brands of energy bars and drink powders were recalled due to potential *Salmonella* contamination of carob ingredients. In addition, peaches, nectarines, and plums packed in California were voluntarily recalled for *Listeria* contamination. Certain brands of ready-to-eat sandwiches and wraps were also recalled due to potential *Listeria* contamination. FDA additionally posted a warning issued by the California Department of Public Health about certain jarred food products susceptible to contamination with Clostridium botulinum. Lastly, a smoked sausage producer recalled its products for failing to label soy as an allergen, and another manufacturer recalled boneless turkey breasts that failed to list milk as an ingredient.

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

Recent Warning Letters

FDA recently warned several seafood processing facilities, including sites in Japan and Ecuador, for failing to comply with HACCP requirements and current good manufacturing practice regulations. The Agency also cited a canned food company for deviating from special rules for the packaging of thermally processed low-acid foods.

FDA continues to post warning letters directed to dairies for illegal drug residues in animals intended for human consumption. Since the last *Update*, FDA has warned four dairies that it has examined tissues samples of dairy cows sold for slaughter and found drug residues that exceeded its allowable tolerances.

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