



FOOD, DIETARY SUPPLEMENT & COSMETICS REGULATORY UPDATE

Top Stories

Sebelius Steps Down, Obama Nominates Burwell for HHS Top Post

On April 11, Kathleen Sebelius resigned from her post as Secretary of Health and Human Services ("HHS"), a leadership position that oversees FDA and generally has ultimate authority over the agency's actions (although rarely does the Secretary of HHS opt to exercise such authority). President Obama swiftly nominated [Sylvia Mathews Burwell](#), current director of the Office of Management & Budget, to take over the position, and she awaits confirmation.

NRDC Presses FDA on GRAS Oversight

In an [April report](#) issued by the Natural Resources Defense Council ("NRDC"), the environmental and public health organization calls on FDA to address a "GRAS loophole," referring to an issue that arises when a company withdraws a GRAS notice to avoid further review of its self-determination that an ingredient it uses in food is GRAS, short for "generally recognized as safe." In such cases, FDA does not publicly disclose any concerns that could have prompted the company's withdrawal.

Moreover, this withdrawal does not prevent the company from marketing the product for use in food. NRDC estimates that about 10 percent of food additives are based upon undisclosed GRAS determinations and urges FDA to require that companies inform the agency of determinations, publish safety concerns even when a company withdraws a notice, and limit conflicts of interest that arise when a company conducts its own safety determinations.

New House Bill Would Preempt State GMO Labeling Laws

On April 9, [U.S. House Representative Mike Pompeo of Kansas](#) introduced a bill that would give ultimate authority of genetically modified organism ("GMO") labeling to FDA, which favors a voluntary approach to the issue. The 21-page bill, [H.R. 4432](#), has the support of the food, biotechnology, and agriculture industries and attempts to nullify state-level efforts to require mandatory labels for foods containing GMOs. The introduction of the bill coincides with [Vermont being on the brink of becoming the first state](#) to successfully pass a [mandatory GMO labeling bill](#). Senator Barbara Boxer of California has also introduced a bill—[S. 809](#)—that seeks to create a federal standard that would mandate the labeling of foods that contain GMOs. Unlike Pompeo's bill, Boxer's has a companion bill in the House ([H.R. 1699](#)).

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Resources

- [Jones Day's Health Care Practice](#)
 - [Jones Day's Life Sciences Practice](#)
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FDA Enforces Against Liquid "Supplement" Maker for Selling a Conventional Food Beverage with Unapproved Food Additive

On March 27, within months of finalizing [relevant guidance documents](#), FDA issued a [warning letter](#) to the maker of *Lean Slow Motion...Potion* for using an unapproved food additive in a product FDA considered to be a conventional food beverage, in spite of the manufacturer's labeling the product as a dietary supplement. In its first warning letter on this issue since the liquid dietary supplements guidance was finalized in January, FDA warned the manufacturer that the beverage drinks are adulterated under federal law because they contain melatonin, which is not approved for use in food. Any substance added to a food product must comply with a food additive regulation or be recognized as GRAS. FDA included in the warning letter a list of factors it evaluated to determine the product was represented for use as a conventional food and not a liquid dietary supplement, which reflected items presented in the guidance.

FDA Issues Draft Guidance on Honey

On [April 9](#), FDA released [draft guidance](#) for industry on proper labeling of honey and honey products. The guidance was issued in response to a [2006 petition by the American Beekeeping Federation](#) and other honey-related associations requesting that FDA adopt a U.S. standard of identity for honey. FDA denied the petition in October 2011, concluding that the petitioners' goals could be met by existing authorities, and a standard of identity for honey would not promote honesty and fair dealing in the interest of consumers. More than two years later, the agency issued this guidance "[t]o address the labeling issues relevant to the petition and to reinforce existing laws and regulations to the industry." The guidance defines honey, summarizes FDA's authority over honey and honey products, and offers advice on labeling issues such as the floral source of honey, blends of honey and other sweeteners, and blends of honey and other ingredients.

Other News

[FDA Asked to Drop Food & Cosmetics From IND Guidance](#)

[FDA Guidance Clarifies Intent of Bioterrorism Law Affecting Dietary Supplements](#)

[USDA Intends to Finalize Proposed Rule to Increase Poultry Inspection Line Speeds](#)

[FSA Announces New Round of Tests to Check Beef for Horse Meat](#)

[Cargill Expects Flour Merger with ConAgra to be Finalized in Six to Eight Weeks](#)

[Increase in Obesity Class-Action Lawsuits](#)

[FDA's New Probe into Evaporated Cane Juice Lawsuits Should Stop Tidal Wave of Lawsuits, Attorney Says](#)

[Beer Brewers Protest Proposed Animal Feed Rule](#)

[FDA Warns Makers of Craze for Using Unapproved Drugs in Dietary Supplements](#)

Regulatory Updates

FDA Issues Draft Guidance for Proper Labeling of Honey and Honey Products

In the [April 9 Federal Register](#), FDA issued Guidance [for Industry: Proper Labeling of Honey and Honey Products](#) to advise firms on the proper labeling of honey products to reduce adulteration and misbranding. The guidance was developed in response to a 2006 Citizen Petition requesting that FDA adopt a U.S. standard of identity to prevent honey labeling fraud. **Comments due June 9.**

FDA Amends Food Additive Rule on Ionizing Radiation for Crustaceans

In the [April 14 Federal Register](#), FDA amended the food additive regulations to provide for the safe use of ionizing radiation for control of food-borne pathogens in crustaceans at a maximum absorbed dose of 6.0 kiloGray (kGy). The amendments are in response to a petition filed by the National Fisheries Institute. **Effective April 14.**

FDA Responds to Public Comments on HACCP for NRTE Comminuted Poultry Products

In the [April 21 Federal Register](#), FDA responded to comments on its [HACCP Plan Reassessment for Not-Ready-to-Eat \("NRTE"\) Comminuted Poultry Products and Related Agency Verification Procedures](#). The 2012 notice provided updated information on the Agency's sampling and testing of these products, and on how it is verifying that establishments are addressing the possible presence of *Salmonella* and *Campylobacter* in them.

FDA Amends Color Additive Regulations to Expand Safe Uses of Spirulina Extract

In the [April 11 Federal Register](#), FDA issued a final rule providing for the safe use of spirulina concentrate, prepared from a filtered aqueous extract of the dried biomass of an edible blue-green cyanobacterium as a color additive in food in response to GNT USA, Inc. **Effective May 13.**

FDA Issues Final Rule on NADAs and ANADAs

In the [April 15 Federal Register](#), FDA issued a final rule and technical amendment to the animal drug regulations to reflect approval of gentamicin and xylazine. The regulations were also amended to reflect previously approved revised food safety warnings for ceftiofur sodium powder. **Effective April 15.**

FDA Withdraws Approval of 19 NADAs for Medicated Articles and Feeds

In the [April 10 Federal Register](#), FDA withdrew approval of 19 new animal drug applications for certain Type A medicated articles and Type B medicated feeds at the sponsors' request because these products are no longer manufactured or marketed. **Effective April 21.**

USDA's APHIS Consolidates Permit Procedures for Transporting Plants

In the [April 10 Federal Register](#), APHIS issued a final rule consolidating the regulations concerning the issuance of permits for the importation and interstate movement of a wide variety of regulated plants, plant products, and other articles. **Effective May 12.**

USDA's Commodity Credit Corporation Issues Final Rule on Emergency Assistance

In the [April 14 Federal Register](#), USDA's CCC issued a final rule, effective when published, implementing specific requirements for the Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program, Livestock Forage Disaster Program, Livestock Indemnity Program, Tree Assistance Program, and general provisions for Supplemental Agricultural Disaster Assistance Programs authorized by the Agricultural Act of 2014. **Effective April 14.**

USDA's APHIS Clears Certain Importation Restrictions on Unshu Oranges from Japan

In the [April 10 Federal Register](#), FDA issued a proposed rule to amend its regulations concerning the importation of citrus fruit to remove certain restrictions on the importation of Unshu oranges from Japan. **Comments due June 9.**

USDA's APHIS Allows Importation of Jamaican Mangoes

In the [April 15 Federal Register](#), APHIS published a proposed rule amending regulations concerning importation of fruits and vegetables to allow the importation of fresh mangoes from Jamaica into the continental United States. **Comments due June 16.**

FDA Releases Guide on Hypoglycin A in Ackee Products

In the [April 15 Federal Register](#), FDA published its [Compliance Policy Guide for Ackee Products](#), which provides guidance on enforcement criteria related to hypoglycin A, a toxin present in the tropical fruit.

USDA announced the opportunity to comment on the following proposed information collections:

- [Disaster Assistance—General](#) (**comments due May 9**)
- [National Animal Health Monitoring System; Bison 2014 Study](#) (**comments due May 15**)
- [Federal Crop Insurance Corp. Standard Reinsurance Agreement](#) (**comments due June 6**)
- [Extension for Index of Legally Marketed Unapproved New Animal Drugs for Minor Species](#) (**comments due June 6**)
- [Current Good Manufacturing Practice Regulations for Medicated Feeds](#) (**comments due June 6**)
- [Transfer of Farm Records Between Counties](#) (**comments due June 9**)
- [Customer Satisfaction Surveys](#) (**comments due June 16**)
- [Recordkeeping and Records Access Requirements for Food Facilities](#) (**comments due June 16**)

- Livestock, Poultry, and Seed Program (*comments due June 17*)
- Farm Service Agency Volunteer Program (*comments due June 20*)
- Meat Slaughter Industry Survey (*comments due May 21*)
- Tenure, Ownership, and Transition of Agricultural Land survey (*comments due June 20*)

FDA announced the opportunity to comment on the following proposed information collections:

- Cosmetic Labeling Regulations (*comments due June 16*)
- Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation (*comments due June 16*)

USDA Issued the following Notices of Funds Availability and Invites Applications:

- Foreign Market Development Cooperator Program
- Technical Assistance for Specialty Crops Program
- Quality Samples Program
- Market Access Program

Other USDA Announcements:

- Federal Crop Insurance Corporation Proposes to Amend the Common Crop Insurance Regulations, Pear Crop Provisions (*comments due May 12*)
- Grain Inspection Service Survey and Application for Designation (*comments due May 15*)
- Overdue Domestic Date Handler Assessments (*comments due June 6*)
- FSIS Best Practices Guidance for Controlling *Listeria monocytogenes* (*Lm*) in Retail Delicatessens (*comments due June 20*)
- FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling (*comments due June 20*)
- Notice of Appointment of Members to the National Agricultural Research, Extension, Education, and Economics Advisory Board
- Expansion of Areas in the Philippines Considered Free of Mango Seed Weevil and Mango Pulp Weevil and Establishment of a Lower Irradiation Dose as a Treatment for Mango Pulp Weevil
- Kiwifruit Grown in California—Continuance Referendum

Upcoming Meetings, Workshops, and Conferences

The [National Organic Standards Board](#) will hold its annual meeting on **April 29–May 2** in San Antonio, TX. **Written comments and sign up for oral public comments due April 8.**

The [Agricultural Air Quality Task Force](#) will meet to continue discussions on critical air quality issues in relation to agriculture on **April 30 and May 1** in Boise, ID. Special emphasis will be placed on obtaining a greater understanding about the relationship between agricultural production and air quality. The meeting is open to the public, and a draft agenda is included in this notice.

The [Plant Variety Protection Board](#) will hold an open teleconference meeting on **May 13**.

The [National Agricultural Research, Extension, Education, and Economics Advisory Board](#) will meet **May 5–7** in Wooster, OH.

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 professionals.

The [General Conference Committee of the National Poultry Improvement Plan \("NPIP"\)](#) and the NPIP's **42nd Biennial Conference** will be held on **July 10–12** in Charlotte, NC. Topics for discussion at the upcoming meeting include a *Salmonella* update from the industry and CDC and approval of rapid testing devices as well as APHIS budget and cooperative agreements updates.

Enforcement Updates

Recent Product Recalls

In the last two weeks, several products were recalled for potential bacterial contamination, including for *Salmonella* contamination. Several snack foods were recalled for undeclared allergens (milk, nuts, and soy). Mislabeled hummus was also recalled for having the ingredient panel from another product, which did not warn that the product contains cheese.

Several dietary supplement products were recalled due to unsafe, contaminated, undeclared, or mislabeled ingredients.

Two animal feeds were recalled, one for inadequate vitamin and mineral levels and another due to the presence of high levels of copper.

Lastly, improper display of the USDA inspection label resulted in a salami recall.

For a complete list of product recalls, click [here](#) for FDA-regulated products, and [here](#) for USDA-regulated products.

Recent Warning Letters

The FDA continues to cite seafood processing facilities for violations of the Seafood HACCP/CGMP for insanitary conditions, adulteration, and recordkeeping violations. The last two weeks' warning letters include seven such citations. Dairies also continue to be a target of warning letters, with four recent warning letters for illegal drug residues. Another executive air transportation firm was cited earlier in the month for sanitation violations relating to potable water and lavatories.

Other warning letters were for a variety of violations. One warning letter addressed a medicated feed mill for erroneous comingling of feed, which produced an unapproved drug combination, meaning the feed was adulterated, misbranded, and mislabeled. FDA pointed out that the staff at the mill was not properly trained, leading to unsafe conditions in feed handling. The maker of a beverage containing melatonin and purporting to be a dietary supplement received a warning letter for the unapproved food additive as well as health claims, adulteration, and misbranding after FDA determined that the product was a conventional food. Excessive pesticides led to warning letters for a parsnips grower and an apple cider maker. Lastly, FDA warned a large food manufacturer for insanitary manufacturing conditions.

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

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