

To: Our Clients and Friends

July 12, 2010

Food, Dietary Supplement and Cosmetic Regulatory and Policy Bulletin



Top News

President Obama Urges Senate to Pass Food Safety Bill

On July 7, 2010, President Obama issued a statement in conjunction with the one-year anniversary of the Food Safety Working Group's key findings on how to upgrade the food safety system. Obama remarked on the steps his Administration has taken steps to reduce pathogens in food and lauded FDA's pilot study on a tracing system and the enhanced and updated www.foodsafety.gov site that provides consumers rapid information on food recalls. He then went on to say that "there is more to be done. [S. 510, the FDA Food Safety Modernization Act] would complement the work already undertaken by the Food Safety Working Group. The bill addresses longstanding challenges in the food safety and defense system by promoting a prevention-oriented approach to the safety of our food supply and provides the Federal Government with the appropriate tools to accomplish its core food safety goals."

FDA Seeks Public Input on Restaurant Menu Labeling

In the [July 7, 2010 Federal Register](#), FDA invited the public to submit comments and information to help the agency implement a new federal law that requires the posting of calorie content and other nutrition information on menu items at certain chain restaurants and similar retail food operations and vending machines. Toward this end, FDA opened a docket to gather public comment and information. The new law, part of the Affordable Care Act signed into law March 23, 2010, requires restaurants and similar retail food establishments which are part of a chain with 20 or more locations that offer substantially the same menu items to list calorie content information on menus and menu boards, including drive-through menu boards. More information is available on the web site for [Docket No. FDA-2010-N-0298](#) and on [FDA's web site](#). Written or electronic comments must be received by September 7, 2010.

FDA Issues Draft Guidance on Judicious Use Antimicrobials in Animals

On June 28, 2010, [FDA issued draft guidance](#) intended to help reduce the development of resistance to medically important antimicrobial drugs used in food-producing animals. The draft guidance outlines FDA's current thinking on strategies to assure that antimicrobial drugs that are important for therapeutic use in humans are used judiciously in animal agriculture. The FDA acknowledged the existing efforts, but emphasized that additional steps are needed. The guidance recommends phasing in measures to limit antimicrobial drugs in food-producing animals to uses considered necessary for assuring animal health and only with veterinary oversight or consultation. [The Washington Post](#) reported the story.

NOAA, FDA, and Gulf Coast State Officials Affirm Commitment to Safe Gulf Seafood

Gulf State health and fisheries officials joined with senior leaders from several federal agencies to [affirm a shared commitment to ensuring the safety of seafood coming out of the Gulf of Mexico](#), through closures of affected waters, surveillance, and with an eye toward reopening closed waters as soon as possible, consistent with public health goals. Agency officials met last week in New Orleans with state health officers and state fisheries to coordinate implementation of a joint protocol for sampling and reopening that will apply to both state and federal waters.

FDA Issues Guidance on Submitting Data for Food Additive Petitions, GRAS Notices

FDA announced that it has revised its [Guidance for Industry Enzyme Preparations: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices](#), which was last updated in January 1993. The guidance describes chemical and technological data that the FDA's Office of Food Additive Safety (OFAS) at the Center for Food Safety and Applied Nutrition (CFSAN) considers when evaluating food additive petitions and GRAS notices for enzyme preparations. The guidance does not discuss data and information relevant to microbiological, toxicological and environmental considerations nor the safety of substances used to immobilize enzymes/

FDA Issues Guidance on Advisory Levels for Vomitoxin in Grains

On July 7, 2010, FDA published [Guidance for Industry and FDA: Advisory Levels for Deoxynivalenol \(DON\) in Finished Wheat Products for Human Consumption and Grains and Grain By-Products used for Animal Feed](#). DON is commonly referred to as vomitoxin. In response to a letter from the animal feed industry requesting that FDA review the current guidelines for DON, FDA decided that the advisory levels for DON in grains and grain by products destined for cattle can be revised and provided new advisory levels that replace those issued in 1993.

New Final Rule to Ensure Egg Safety, Reduce Salmonella Illnesses Goes Into Effect

New food safety requirements for egg safety became effective on July 9, 2010, through a rule for egg producers having 50,000 or more laying hens – about 80 percent of production. Among other things, it requires them to adopt preventive measures and to use refrigeration during egg storage and transportation. Additional information is available in the [FDA press release](#).

FDA Examining Probiotics, Exploring Future Regulation

As the University of Maryland, a federally funded project to research probiotics was launched in late June. The outcome of the research is expected to result in FDA guidance on permissible health claims for probiotics. While there is some suggestion that FDA may separate probiotics regulation from that of dietary supplements, it is more likely that the probiotics guidance will be wrapped in with dietary supplement regulation.

USDA Posts Transcript for HACCP Validation Draft Propose Guidance

On June 14, 2010, FSIS held the first of a series of public meetings to discuss and receive public comment on the agency's draft proposed guidance concerning Hazard Analysis and Critical Control Points (HACCP) Validation. The agency made a preliminary draft of the validation guidance available in March to receive public input earlier in the guidance development process, as requested by a number of stakeholders. The guidance does not create any new requirements on establishments, but rather clarifies existing requirements and provides direction on how producers, especially small producers, can meet them. The transcripts from this meeting are now available on FSIS' Web site at http://www.fsis.usda.gov/News_&_Events/past_events/index.asp.

USDA Finalizes Ground Beef Standards for School Lunch and Nutrition Programs

USDA has finalized tougher new standards for ground beef purchased by the Agricultural Marketing Service (AMS) for Federal food and nutrition assistance programs including the National School Lunch Program. The new requirements will be applicable to AMS ground beef contracts awarded on or after July 1, 2010. The new purchasing requirements can be found in their entirety at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5085021>.

FDA, FSIS, and CDC Will Hold Public Meetings to Measure Food Safety Efforts

FDA, USDA's Food Safety and Inspection Service (FSIS), and Centers for Disease Control and Prevention (CDC) announced two joint public meetings to hear stakeholder presentations on measuring progress on food safety – one in Chicago on July 21, and the second in Portland, OR on October 20. These public meetings are extensions of the initial one-day public workshop held on March 30, 2010, where FSIS, FDA, and CDC discussed their collaborations on the methodological and data challenges involved in the development of feasible and effective food safety metrics. The agencies have been collaborating to reduce foodborne illness as part of the Food Safety Working Group, which has recommended a public health-focused approach to food safety based on the principles of prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. The agencies will present current thinking, focusing on how these metrics might be applied to evaluate the success of FDA's shell egg safety rule, FSIS implementation of broiler chicken controls, and CDC's efforts to collect and analyze human disease data. Additionally, the agencies will present information about the shared list of metrics that was developed by them to support the work of the Food Safety Working Group. An [FSIS press release](#) and [Federal Register Notice](#) provide additional information.

USDA, HHS Announce Progress of Food Safety Working Group Recommendations

On July 9, 2010, Agriculture Secretary Tom Vilsack and Secretary of HHS Kathleen Sebelius commended federal food safety agencies for their accomplishments supporting the charge of President Obama's Food Safety Working Group, which advises the President on how to upgrade the U.S. food safety system. In 2009, the Food Safety Working Group made progress in the areas of prioritizing prevention, strengthening inspection and enforcement, and improving response and recovery. The [news release](#) provides a brief summary of the accomplishments.

Honey Industry Asks FDA to Regulate Purity Standards in Order to Stay Competitive

Due to lower honey production in the United States and an increased amount of honey being imported from China, domestic honey producers are lobbying for an FDA regulated purity standard. [The Washington Post](#) reports that "with vocal assistance from Sen. Charles E. Schumer (D-N.Y.), U.S. beekeepers, honey producers and packers are pressing the Obama administration to crack down on "honey launderers" in China who ship the product through third countries to avoid the sting of anti-dumping duties."

Briefly Noted

[EU proposes new food labeling regulations that would require eggs and rolls to be sold by weight and not the dozen.](#)
[USA Today finds government documents that show that airline food could pose health threats.](#)
[CRN, Virgo publishing announce webinar for manufacturers, retailers on roles and responsibilities for supplement claims.](#)
[USDA's Meat and Poultry Hotline Celebrates 25 Years.](#)
[USDA Offers Food Safety Tips in Aftermath of Hurricane Alex.](#)
[Federal Agents Seize Bee-Shield Hand Sanitizer from Puerto Rican Company.](#)

Recent Recalls

[Miravalle Chile California and Chile Nuevo Mexico Peppers](#) due to salmonella contamination (July 8, 2010).
[Señor Mexicano Avocado Pulp](#) due to listeria contamination (July 8, 2010).
[Ready Pac Baby Spinach](#) due to E. coli contamination (July 7, 2010).
[K. Heeps fully cooked turkey breast products](#) due to listeria contamination (July 7, 2010).
[M&K II Co. beef jerky products](#) due to E. Coli contamination (July 6, 2010).
[Rocky Mountain Natural Meats ground/tenderized steak bison products](#) due to E. coli contamination (July 2, 2010).
[Merrick Pet Care Beef Filet Squares for Dogs](#) due to salmonella contamination (July 2, 2010).
[Fairway Energy Mix, Setton Farms Total Energy Mix](#) due to undeclared allergens and other ingredients (July 2, 2010).
[Pro-Pet Adult Daily Vitamin Supplement tablets for Dogs](#) expanded due to salmonella contamination (July 2, 2010)
[Azteca Linda Queso Fresco and Queso Hebra](#) due to potential to listeria contamination (July 1, 2010).
[Oregon Freeze Dry Beef Stroganoff with Noodles](#) due mislabeling (June 30, 2010).
[Cervelat Summer Sausage](#) due to an undeclared milk (June 30, 2010).
[Feline's Pride Raw food with ground bone for cats and kittens, Natural Chicken](#) due to salmonella (July 1, 2010).

[Chicken of the Sea 12-ounce solid white tuna](#) in water due to inadequate seal tightness (June 30, 2010).

[Fuma Custard Pie](#) due to undeclared milk powder (June 30, 2010).

[Roba Dolce Double Chocolate Chunk Gelato](#) due to undeclared peanuts (June 30, 2010).

FDA Issues Consumer alert that [Que She, marketed as an herbal weight loss supplement](#), contains active pharmaceutical ingredients not listed on the product label that could harm consumers, especially those with cardiovascular conditions.

Recently Posted Warning Letters

FDA warned [Tom Schantz Farm \(d/b/a Riverview Dale Farm\)](#), [Busman Dairy, Keith and Patricia Haldiman, Coldstream Farms L.L.C.](#), and [John L. Skogen](#) that FDA investigators found that their dairy operations offered an animal for sale for slaughter as food that was adulterated because it contained an unsafe or unsafe amount of an animal drug and the animal was held under insanitary conditions.

FDA warned [Tejas Industries Inc.](#) that their dog chew pet treats were adulterated due to salmonella contamination.

FDA warned [Lactasoy Company](#) and [Oxford Falls](#) that FDA investigators found serious deviations from the low-acid canned food regulations at their low-acid canned food facility.

FDA warned [Union Development Frozen Foods Co., Ltd](#) and [Mamma Lina's, Inc.](#) that FDA inspectors found serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation.

FDA Warned [Basic Food Flavors, Inc.](#) that the hydrolyzed vegetable protein (HVP) processed by their facility is adulterated due to salmonella contamination and that FDA inspectors also found serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods.

FDA Warned [Nicola Pizza Inc.](#) that FDA inspectors also found serious violations of the Current Good Manufacturing Practice (CGMP) regulation for foods.

New Regulatory Notices

FSIS Announces Nominations for Membership on the National Advisory Committee on Microbiological Criteria for Foods

In the [July 8, 2010 Federal Register](#), USDA's Food Safety and Inspection Service announced it is accepting nominations for membership on the National Advisory Committee on Microbiological Criteria for Foods. Nominations, including the nominee's typed resume or curriculum vitae and a USDA Advisory Committee Membership Background Information form AD-755 must be received by **August 9, 2010**. USDA Advisory Committee Membership Background Information form AD-755 is available on-line at: <http://www.ocio.usda.gov/forms/doc/AD-755.pdf>.

USDA Announces Notice of Request for Revision of a Currently Approved Information Collection (Pathogen Reduction/HACCP)

In the [June 29, 2010 Federal Register](#), USDA announced that it is revising the Pathogen Reduction/HACCP systems information collection based on its most recent establishment data. In addition, FSIS is adding information concerning the use of video recordkeeping for HACCP records and Sanitation Standard Operating Systems (SOPs) records. Interested parties must submit comments by **August 30, 2010**.

FDA Seeks Public Input on Restaurant Menu Labeling

In the [July 7, 2010 Federal Register](#), FDA invited the public to submit comments and information to help the agency implement a new federal law that requires the posting of calorie content and other nutrition information on menu items at certain chain restaurants and similar retail food operations and vending machines. Toward this end, FDA opened a docket to gather public comment and information. The new law, part of the Affordable Care Act signed into law March 23, 2010, requires restaurants and similar retail food establishments which are part of a chain with 20 or more locations that offer substantially the same menu items to list calorie content information on menus and menu boards, including drive-through menu boards. More information is available on the web site for [Docket No. FDA-2010-N-0298](#) and on [FDA's web site](#). Written or electronic comments must be received by **September 7, 2010**.

FSIS Announces Information on Federal Inspection Exemptions for Retail Stores

In the June 29, 2010 Federal Register, USDA's Food Safety and Inspection Service (FSIS) announced the dollar limitations on the amount of meat and meat food products, poultry and poultry products that a retail store can sell to hotels, restaurants, and similar institutions without disqualifying itself for exemption from Federal inspection requirements. In accordance with FSIS's regulations, for calendar year 2010, the dollar limitation for meat and meat food products remains at \$60,200 but for poultry products is being increased from \$49,400 to \$50,200. FSIS is retaining or changing the dollar limitations from calendar year 2009 based on price changes for these products evidenced by the Consumer Price Index. The notice is **effective June 29, 2010**.

FSIS Policy Updates

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

- [New Zealand](#) (Jul 6, 2010)
- [Russia](#) (Jul 2, 2010)
- [Russia \(Pork\) Plant List](#) (Jul 2, 2010)
- [Mexico](#) (Jun 30, 2010)
- [Uruguay](#) (Jun 30, 2010)

FSIS recently published the following new notice(s):

- [FSIS Notice 31-10](#), *General Food Defense Plan*
- [FSIS Notice 32-10](#), *Certifying Products Under Export Verification (EV) Programs*
- [FSIS Notice 33-10](#), *Correction Required for Russian Beef and Poultry Export Certificates*
- [FSIS Notice 35-10](#), *Export Library Revisions in June 2010*

Regulatory Notices with Open Comment Periods

USDA Publishes New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments; New Compliance Guides

In the [May 14, 2010 Federal Register](#), USDA's Food Safety and Inspection Service (FSIS) announced new performance standards for the pathogenic micro-organisms Salmonella and Campylobacter for use in young chicken and turkey slaughter establishments. The new performance standards were developed in response to a charge from the Food Safety Working Group. The Agency tentatively plans to implement these new performance standards for chilled carcasses in July 2010. The new standards are based on recent FSIS Nationwide Microbiological Baseline Data Collection Programs: The Young Chicken Survey and the Young Turkey Survey. The Agency invites comments on the new performance standards. FSIS is also announcing that it has posted on its Web site the third edition of the compliance guide for controlling Salmonella and Campylobacter in poultry and a compliance guide on pre-harvest management to reduce E. coli O157:H7 contamination in cattle. Interested parties must submit electronic or written comments by **July 13, 2010**.

FDA Announces Information Collection Activities Concerning Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

In the [June 18, 2010 Federal Register](#), FDA announced that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance concerning regulations that place general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products. Interested parties must submit electronic or written comments by **July 19, 2010**.

FDA Transparency Task Force Publishes Draft Proposals; Seeks Comments

In the [May 21, 2010 Federal Register](#), FDA announced that, as part of the second phase of the Transparency Initiative, the FDA is announcing the availability of a report entitled “FDA Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration.” The report includes 21 draft proposals about expanding disclosure of information by the agency while maintaining confidentiality of trade secrets and individually identifiable patient information. FDA is seeking public comment on the draft proposals, as well as on which draft proposals should be given priority. Some of the draft proposals may require extensive resources to implement, and some may require changes to regulations or legislation. Interested parties must submit electronic or written comments by **July 20, 2010**.

FDA Extends Comment Period for Fresh Produce Packing and Production

In the [May 20, 2010 Federal Register](#), FDA announced that the agency is extending to July 23, 2010, the comment period for a notice that appeared in the Federal Register of [February 23, 2010](#). In that notice, FDA established a docket to obtain comments and information about current practices and conditions for the production and packing of fresh produce. The agency is extending this comment period to give interested parties additional time to provide the information requested by FDA in that notice. Interested parties must submit electronic or written comments by **July 23, 2010**.

FDA Announces Information Collection about Food Code Adoption

In the [June 24, 2010 Federal Register](#), FDA announced an information collection to facilitate a current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments. Such an inventory is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code. Interested parties may submit comments by **July 26, 2010**.

FDA Announces Proposed Information Collection on Food-Contact Article Substances

In the [June 24, 2010 Federal Register](#), FDA announced a proposed collection of information on the threshold of regulation for substances used in food-contact articles. FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves. Interested parties may submit comments by **July 26, 2010**.

FDA Issues Second Edition of Draft Guidance for Industry on Reportable Food Registry

In the [May 25, 2010 Federal Register](#), FDA announced the availability of a draft guidance, “Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2).” The draft guidance provides information to the industry in complying with the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007 (FDAAA). Further, the draft guidance addresses inquiries that the agency has received through its Reportable Food Registry help desk and/or by other means since the implementation of the Reportable Food Registry on September 8, 2009, and provides information on the new Safety Reporting Portal. The agency is also seeking comments from industry on the Reportable Food Registry requirements, and specifically on the issue of “transfer” as discussed in the current Edition 1, and draft Edition 2 guidance. Although you can comment on any guidance at any time, to ensure that the agency considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by **July 26, 2010**.

FSIS Announces Compliance Guide for Mobile Slaughter Units

In the [May 25, 2010 Federal Register](#), USDA's Food Safety and Inspection Service (FSIS) announced the availability of a compliance guide on mobile slaughter units. FSIS will post this compliance guide on its Significant Guidance Documents Web page http://www.fsis.usda.gov/Significant_Guidance/index.asp. FSIS encourages those who own or manage mobile slaughter units to avail themselves of this guidance document in meeting the pertinent regulatory requirements. FSIS is also soliciting comments on this compliance guide. The Agency will consider carefully all comments submitted and will revise the guide as warranted. Interested parties must submit comments by **July 26, 2010**.

FDA Seeks Comment on Proposed Information Collection on Additive Petitions

In a [June 14, 2010 Federal Register Notice](#), FDA solicited comments on the information collection provisions of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations, submission of information to a Master File in support of petitions, and electronic submission using FDA Form 3503. This notice also notifies the public of and solicits comments on FDA's proposed changes to Form FDA 3503 and elimination of Form FDA 3504. Interested parties must submit electronic or written comments on the collection of information by **August 13, 2010**.

FDA Issues Advance Notice of Proposed Rulemaking to Implement 2005 SFTA

In the [April 30, 2010 Federal Register](#), FDA announced an advance notice of proposed rulemaking to implement the Sanitary Food Transportation Act of 2005 (2005 SFTA, see top news story above). FDA is specifically requesting data and information on the food transportation industry and its practices. FDA also is requesting data and information on the contamination of transported foods and any associated outbreaks. FDA is taking this action as part of its implementation of the 2005 SFTA, which requires the Secretary of HHS to issue regulations setting forth sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and others engaged in food transport. This action is also part of a larger agency effort to focus on prevention of food safety problems throughout the food chain. The regulations would address the risks to human or animal health associated with the transportation of food. Interested parties must submit electronic or written comments by **August 30, 2010**.

Upcoming Meetings

FSIS to Host Livestock Slaughter Inspection Training Designed for State Inspectors

USDA's FSIS is partnering with the [International Food Protection Training Institute \(IFPTI\)](#) in Battle Creek, Mich., and the [Association of Food and Drug Officials](#) to provide FSIS meat and poultry inspection training courses for state inspection personnel. This week-long session, "Livestock Slaughter Inspection Training" will be held **July 12 to 16, 2010** and is at no cost to the states. Applications should be sent directly to IFPTI and must be received by May 28. To download and submit an application, visit http://www.ifpti.org/20100712bc_distributed.pdf.

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. Interested parties may submit written comments to the docket up to 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](#).

FSIS, CDC, FDA to Hold Public Meetings on Measuring Food Safety Progress

Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), are jointly hosting two public meetings to obtain stakeholder input. The first is on **July 21, 2010, in Chicago, IL**. The second will be held on **October 20, 2010, in Portland, OR**. The Agencies are requesting information

from all stakeholders, including the regulated food industry, State regulators, and consumer groups, on appropriate metrics to be used to assess performance in food safety. The Agencies are also interested in input on stakeholders' understanding and perceptions of metrics currently being used by the Federal Agencies. Although the Agencies are primarily interested in obtaining stakeholder input, the Agencies will present a limited amount of background on the Food Safety Working Group's charge to create meaningful metrics to measure the effectiveness of the Nation's food safety system and the Agency's current thinking on these issues. More information is available in the [Federal Register Notice](#).

FDA to Hold Food Labeling Workshop

FDA Office of Regulatory Affairs, Southwest Regional Small Business Representative (SWR SBR) Program, in collaboration with the University of Arkansas (UA), is announcing a public Food Labeling Workshop intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups. The public workshop will be held on **August 4 and 5, 2010**, from 8 a.m. to 5 p.m. in Fayetteville, AR (located downtown). For additional information, see the [Federal Register Notice](#) or contact David Arvelo at david.arvelo@fda.hhs.gov.

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.

More Information

Archived issues of the Bryan Cave Food, Dietary Supplement, and Cosmetic Regulatory and Policy Bulletin are available at www.bryancave.com on the [FDA Practice Bulletins web page](#). If you have any questions regarding any of these issues, please contact:

Mark Mansour	Partner	mark.mansour@bryancave.com	1 202 508 6019	Washington
Megan A. Gajewski	Associate	megan.gajewski@bryancave.com	1 202 508 6302	Washington
Patrice M. Hayden	Associate	pmhayden@bryancave.com	1 202 508 6147	Washington
Emily K. Strunk	Associate	emily.strunk@bryancave.com	1 202 508 6360	Washington

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