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MEMORANDUM

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Re: **FDA Releases Series of Draft FSMA Guidance Documents**

The Food and Drug Administration (FDA) recently released the following draft guidance documents to assist industry in implementing the FDA Food Safety Modernization Act (FSMA) final rules:

- The first five draft chapters and three appendices of Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food;
- Draft Guidance for Industry for Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities;
- Draft Guidance for Industry #235 - Current Good Manufacturing Practice Requirements for Food for Animals; and
- Draft Guidance for Industry # 239 – Human Food By-Products for Use as Animal Food.

This memorandum provides a brief overview of the subject matter areas covered by each of the draft guidance documents and their respective comment deadlines.

Hazard Analysis and Risk-Based Preventive Controls for Human Food

FDA released draft versions of the first five of 14 chapters in a guidance document intended to assist industry in complying with the preventive controls and supply-chain program regulations under the Preventive Controls for Human Food final rule. The first five chapters cover:

(1) The Food Safety Plan (FSP): This chapter includes an explanation of the contents of an FSP, who should prepare the FSP, and how FSPs differ from hazard analysis and critical control point (HACCP) plans.

(2) Conducting a Hazard Analysis: This chapter provides an overview of the hazard analysis, as well as recommendations for activities prior to conducting the hazard analysis, identifying potential hazards, evaluating potential hazards to determine whether they require a preventive control, and identifying preventive control measures.

(3) Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food: This chapter summarizes the biological, chemical, and physical hazards that are commonly of concern in food and food plants (including economically motivated adulterants) and that FDA advises should be addressed in a hazard analysis.

(4) Preventive Controls: This chapter is intended as a resource to help industry identify and implement preventive controls and includes an overview of common preventive controls that can be used to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in food products and the food production environment.

(5) Application of Preventive Controls and Preventive Control Management Components: This chapter addresses the application of preventive controls and provides an overview of preventive control management components, including monitoring, corrective actions, corrections, and verification activities, as well as their associated records. Some of the forthcoming chapters will provide more detailed examples of the application of preventive controls and associated preventive control management components discussed in this chapter.

The forthcoming chapters of the guidance will cover: (6) Use of Heat Treatments as a Process Control; (7) Use of Time/Temperature Control as a Process Control; (8) Use of Formulation as a Process Control; (9) Use of Dehydration/Drying as a Process Control; (10) Sanitation Controls; (11) Food Allergen Controls; (12) Preventive Controls for Chemical Hazards; (13) Preventive Controls for Physical Hazards; and (14) Recall Plans. These remaining nine chapters will be released in waves through 2018.

In addition to the first five chapters identified above, the draft guidance also contains three appendices: (1) Potential Hazards for Foods and Processes; (2) Food Safety Plan Forms (these are the same as those developed by the Food Safety Preventive Controls Alliance (FSPCA)); and (3) Bacterial Pathogen Growth and Inactivation. An appendix on Sanitation and Hygienic Zoning is forthcoming.

Comments on the first five chapters and three appendices should be submitted by February 21, 2017.

Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/ Processing For Farms and Facilities

FDA's draft guidance on the classification of activities is intended to assist businesses in determining whether the activities they perform are within the "farm" definition and, in turn, whether they are subject to the registration and preventive controls requirements under the Preventive Controls rules. The draft guidance is of particular significance to those businesses handling raw agricultural commodities (RACs), including nuts, seeds, grains, coffee beans, cocoa beans, and produce.

To help businesses understand the differences between the various types of and the circumstances under which certain activities may or may not fall within the "farm" definition, the guidance provides the following:

- Examples of "harvesting," "packing," "packaging," "holding," and "manufacturing/processing" activities in addition to those examples established in FDA's final FSMA rules;

- An explanation of why some activities are classified in more than one way (e.g., aging/curing/fermenting/oxidizing, coring, cutting, hulling, shelling); and

- Examples explaining which activities are and are not within the "farm" definition for hypothetical farms, mixed-type facilities, and operations conducting various activities, such as those concerning apples, lettuce, walnuts, and tomatoes.

Notably, the draft guidance explains that "harvesting" relates to a place where RACs were grown or raised. FDA interprets harvesting to occur only (1) in the same general physical location as where RACs are grown or raised (though the RACs grown/raised in that location need not be the same RACs, or same type(s) of RACs, harvested in that location); or (2) at operations that meet the criteria in the secondary activities farm definition linking the farm where the RACs were harvested to the secondary activities farm (through both the RACs themselves and the majority ownership requirement). In addition, via the draft guidance, FDA withdraws its prior statements regarding "repacking" and "blast freezing" to clarify that neither activity may be considered "holding."

Comments should be submitted by February 21, 2017.

cGMP Requirements for Food for Animals

FDA's draft Guidance for Industry on Current Good Manufacturing Practice Requirements for Food for Animals is intended for use by facilities that must register as food facilities because they manufacture, process, pack, or hold animal food for consumption in the United States. It contains information to assist facilities in determining whether they must comply with the Current Good Manufacturing Practice (cGMP) requirements for animal food. In particular, it includes a discussion of which cGMPs to follow for facilities with both human and animal food operations and for facilities that divert human food by-products for use as animal food. For those facilities that are subject to the animal food cGMPs, the guidance provides additional explanation of the cGMPS and recommendations for compliance in areas such as personnel, plant and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, and holding and distribution, as well as recommendations for compliance with related requirements such as recordkeeping and training.

Comments on the draft guidance should be submitted by November 23, 2016.

Human Food By-Products for Use as Animal Food

The Guidance for Industry on Human Food By-Products for Use as Animal Food provides information to assist facilities that manufacture, process, pack or hold human food and that also divert human food by-products for use as animal food in determining what requirements in the Animal Food Preventive Controls rule apply to them.

The document includes information related to:

- The application of the rule to establishments that are not required to register as food facilities and to U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) establishments that also are required to register with FDA;

- Human food by-products that are subject to only limited holding and distribution cGMPs for animal food because they are:

    - subject to and in compliance with the cGMPs for human food and in compliance with all other applicable human food safety requirements and implementing regulations for human food, or
    - subject to and in compliance with the requirements of section 117.8 and in compliance with all other applicable human food safety requirements and implementing regulations for the off-farm packing and holding of produce;

- Human food facilities subject to the full requirements of the Animal Food Preventive Controls rule for their by-products diverted for use as animal food; and

- The diversion for animal food use of human food and human food by-products with a food safety concern.

With respect to human food and human food by-products with a human food safety concern, the draft guidance explains that such food should be evaluated by establishment management to determine whether it is appropriate to divert to animal food. When management has made a determination that the human food safety concern is not an animal food safety concern, FDA does not expect a diversion request to be submitted to the local FDA district office pursuant to the procedure outlined in Compliance Policy Guide Section 675.200. Similarly, if establishment management is able to rework or reprocess the human food or human food by-product to eliminate the animal food safety concern or can distribute the product to another establishment that will process the human food or human food by-product so that there is no longer an animal food safety concern, then FDA would not expect a diversion request to be submitted.

Comments should be submitted by November 23, 2016.

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We will continue to closely monitor FDA's implementation of FSMA. Should you have any questions or require advice on FSMA compliance, please do not hesitate to contact us.