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**MEMORANDUM**

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**Re: FDA Issues FSMA Guidance Documents on Supplier Verification and Preventive Controls for Animal Food**

The U.S. Food and Drug Administration (FDA) has issued five FDA Food Safety Modernization Act (FSMA) final and draft guidance documents relating to supplier verification under both the Foreign Supplier Verification Program (FSVP) and the Preventive Controls for Human Food (PCHF) rules, as well as draft guidance regarding the Preventive Controls for Animal Food (PCAF) rule.

This memorandum briefly summarizes the issues addressed in each of the following documents:

- FSVP Draft Guidance;
- Chapter 15 (Supply-Chain Program) of the Hazard Analysis and Risk-Based Preventive Controls for Human Food Draft Guidance;
- Guidance on the Application of FSVP Regulation to Importers of Grain Raw Agricultural Commodities;
- Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507 Draft Guidance;
- FSVP Small Entity Compliance Guide (SECG); and,
- Hazard Analysis and Risk-Based Preventive Controls for Animal Food Draft Guidance.

We encourage a close review of each of the documents, as they address important issues affecting compliance with the major FSMA regulations. Note that comments can be submitted at any time on guidance documents. FDA has established dates by when comments are requested to be submitted on the draft guidance documents, which are set out below.

**FSVP Draft Guidance**

FDA has issued a Questions-and-Answers style Draft Guidance on the FSVP rule. 1/ The 108-page Draft Guidance addresses many questions concerning the scope of the regulation, the activities that

1/ Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: Draft Guidance for Industry (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593079.pdf.

must be conducted under an FSVP, identifying the FSVP importer at entry, recordkeeping, and enforcement.

Within these broad categories, the Draft Guidance addresses many questions frequently asked by industry, such as:

- What to do if multiple entities meet the definition of "importer" for a particular food;
- How to determine if foods or entities qualify for various exemptions, such as the exemption for foods for research or evaluation;
- The role of corporate headquarters for supplier verification and handling FSVP for intra-company shipments;
- FSVP requirements for importers who also are receiving facilities under the Preventive Controls regulations;
- How to comply with the supplier evaluation requirements;
- The role that third-parties can play to assist importers with their supplier verification responsibilities;
- FDA's expectations for verification activities such as sampling and testing and on-site audits of suppliers; and
- FDA's enforcement plans in the event of non-compliance by an importer.

*Comment Deadline*: Comments on the Draft Guidance are due May 25, 2018, and must be submitted to Docket No. FDA-2017-D-6592.

**Chapter 15 of PCHF Draft Guidance**

FDA has released Chapter 15 of the Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food. 2/ Chapter 15 focuses on supply-chain programs under Subpart G of PCHF rule. The Draft Guidance includes recommendations for receiving facilities establishing and implementing supply-chain programs for their suppliers. In large part, the content is parallel to the content of the FSVP guidance.

The chapter covers topics such as how a corporate parent can participate in establishing and implementing a receiving facility's supply-chain program, considerations for approving suppliers and determining appropriate supplier verification activities and their frequency, and records documenting the supply-chain program.

*Comment Deadline*: Comments are due May 25, 2018, and must be submitted to Docket No. FDA-2016-D-2343.

**Application of FSVP to Importers of Grain Raw Agricultural Commodities**

FDA has issued Guidance on the application of FSVP to importers of grain raw agricultural commodities (RACs) (e.g., barley, dent- and flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds for oil extraction). 3/ The Guidance announces FDA's intent to

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2/ "Supply-Chain Program for Human Food Products," Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM592660.pdf.

3/ Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities: Guidance for Industry (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593080.pdf.

exercise enforcement discretion regarding the application of the FSVP rule to importers of grains that are imported into the United States as RACs. The enforcement discretion will apply to grain importers that are solely engaged in the storage of grain RACs intended for further distribution or processing and grain RACs importers that do not take physical possession of the grain they import, but instead arrange for the delivery of the grain to others for storage, packing, or manufacturing/processing.

This means FDA will not expect importers of grain RACs (i.e., grain elevators and other facilities solely engaged in the storage of grain RACs intended for further distribution or processing) to meet any of the FSVP requirements. Importers that manufacture/process grain RACs will remain subject to the rule. FDA's exercise of enforcement discretion better aligns the FSVP rule with the exemption from Preventive Controls requirements for facilities solely engaged in the storage of non-produce RACs.

*Comments*: The Guidance is effective immediately. Comments may be submitted at any time to Docket No. FDA-2017-D-6592.

**Draft Guidance on Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Preventive Controls Requirement**

FDA has issued Draft Guidance addressing the term "same level of public health protection," as used in the FSVP and Produce Safety rules. 4/ Under the FSVP rule, importers must implement an FSVP that provides adequate assurances that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the Produce Safety regulation (part 112) or the preventive controls requirements in part 117 or part 507, as applicable. The Produce Safety regulation includes similar provisions whereby farms may use measures different from those required under part 112, provided all relevant requirements are met, including that those measures provide the same level of public health protection as the corresponding FDA-established requirement in part 112.

The Draft Guidance addresses issues such as the data and information that should be used to support a determination that a measure provides the same level of public health as the corresponding requirement, as well as unique considerations relevant to the measure, the entity that conducts the evaluation, and documentation for such a determination.

*Comment Deadline*: Comments are due May 25, 2018, and must be submitted to Docket No. FDA-2017-D-0397.

**FSVP Small Entity Compliance Guide**

FDA has issued a SECG on the FSVP rule. 5/ The SECG provides an overview of the regulation and a discussion of the foods covered by the regulation, with a focus on the modified procedures for very small importers or importers of food from certain small foreign suppliers.

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4/ Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507 Draft Guidance (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593086.pdf.

5/ Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation: Guidance for Industry (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593089.pdf.

*Comments*: Comments may be submitted at any time to Docket No. FDA-2011-N-0143.

**Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Animal Food**

FDA has released the first five chapters of its draft guidance intended to assist animal food facilities to comply with the PCAF rule. 6/ The chapters cover: (1) food safety plan requirements; (2) recommendations for conducting a hazard analysis; (3) hazards associated with the manufacturing, processing, packing, and holding of animal food; (4) examples of preventive controls that may be used to significantly minimize or prevent animal food hazards; and (5) preventive control management components. FDA also announced that forthcoming guidance for the PCAF rule will include an in-depth guidance on supply-chain programs.

*Comment Deadline*: Comments on the first five chapters of the PCAF guidance are due by July 23, 2018, and must be submitted to Docket No. FDA-2016-D-2343.

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We will continue to monitor developments related to FDA's implementation of FSMA. Please contact us if you would like to discuss these guidance documents or if we can provide assistance preparing written comments.

6/ Draft Guidance for Industry #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM593089.pdf.