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MEMORANDUM

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Re: **FDA Announces Enforcement Discretion for Certain FSMA Provisions**

On January 4, 2018, the Food and Drug Administration (FDA) announced through Guidance that it does not intend to enforce particular provisions of the Preventive Controls for Human Food (PCHF), Preventive Controls for Animal Food (PCAF), Produce Safety, and Foreign Supplier Verification Programs (FSVP) regulations issued under the FDA Food Safety Modernization Act (FSMA). 1/ This memorandum provides an overview of the situations in which FDA will exercise enforcement discretion, specifically:

- Written assurance provisions in all four rules related to the downstream control of identified hazards or microorganisms that are a potential risk to public health;
- FSVP requirements for importers of food contact substances (FCS);
- PCAF requirements for certain manufacturing/processing activities performed on human food by-products for use as animal food; and
- Certain facilities that are similar to farms, but that do not meet the "farm" definition.

"Enforcement discretion" means the agency does not intend to enforce requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the implementing regulations. The agency plans to engage in future rulemaking on most of these issues, but rulemaking is a slow process. Therefore, this Guidance is an interim measure whereby FDA can signal its changed position on these issues.

I. Background and Overview

In a final rule published August 24, 2016, FDA extended the compliance dates for certain provisions in these four FSMA regulations while the agency was considering how to address concerns that had

1/ *Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry* (Jan. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM590661.pdf (hereinafter "Guidance").

been raised by industry. 2/ This recently issued Guidance goes further than the August 2016 notice by announcing an enforcement discretion policy with no expiration date, now that FDA has decided that certain requirements under the regulations require modification. Indeed, the Guidance states throughout that the agency will exercise enforcement discretion until it engages in future rulemakings. The Guidance also is broader in scope than the August 2016 action, as since that time FDA has become aware of additional circumstances for which FDA now intends to exercise enforcement discretion.

This guidance is final and effective immediately, though comments can be submitted on guidance at any time. 3/ FDA explains that the Guidance is consistent with other actions it has taken to ensure that the FSMA rules are effective while providing flexibility where necessary and appropriate to support compliance.

The exercise of enforcement discretion only applies to whether FDA will require a facility to comply with the applicable FSMA regulation. It does not affect the facility registration requirements. Thus, a facility that is currently required to register must still do so, regardless of whether the facility is covered by the enforcement discretion policy. Finally, the agency repeatedly emphasizes that regardless of the exercise of enforcement discretion regarding these regulations, it will continue to enforce the statutory prohibition against the introduction or delivery of adulterated food in interstate commerce.

II. Written Assurances

As background, these four FSMA regulations each contain provisions whereby certain hazards do not need to be controlled so long as appropriate disclosures are made to and written assurances are received from the downstream customer. For example, 21 C.F.R. § 117.136 of the PCHF regulation provides that a facility is not required to implement a preventive control if it identifies a hazard requiring a preventive control and this hazard is controlled downstream by a commercial customer, provided the facility:

(1) Provides documentation to its direct customer that the food is "not processed to control [identified hazard]" (the disclosure statement requirement); and
(2) Receives written assurance from its customer that the customer or an entity further down the supply chain will control the hazard (customer assurance requirement).

There are similar provisions in the PCAF rule (§ 507.36) and FSVP rule (§ 1.507). Likewise, the Produce Safety rule provides that farms are exempt from the rule if the produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided that a similar disclosure statement requirement and customer assurance requirement are met (§ 112.2).

FDA explained in its August 2016 final rule extending the compliance date for the written assurance provisions that the Grocery Manufacturers Association (GMA) raised concerns that compliance with the customer assurance requirements under each rule would require "vastly more written assurances and consequently resources" than FDA had anticipated. At that time, FDA extended the compliance dates for written assurances by two years to allow FDA to consider the best approach to

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2/ 81 Fed. Reg. 57784 (Aug. 23, 2016); *see* HL Memo - FDA Extends Certain FSMA Compliance Deadlines (Sept. 7, 2016) https://hlfoodlawblog.lexblogplatform.com/wp-content/uploads/sites/357/2017/02/HL-Memo-FDA-Extends-Certain-Compliance-Deadlines-1.pdf.

3/ FDA is implementing this guidance without prior public comment, as permitted by 21 C.F.R. § 10.115(g)(2), because it determined that public participation is not feasible or appropriate.

address these feasibility concerns. Thus, the compliance dates would have taken effect starting September 2018.

Now, the new Guidance provides that FDA will exercise enforcement discretion for the written assurance requirements in the PCHF, PCAF, Produce Safety, and FSVP regulation until it completes a planned future rulemaking on this issue. In other words, FDA will not enforce the written assurance requirements, even after the compliance date extension expires, until rulemaking is complete. The rulemaking will take into consideration the complex supply chain relationships and resource requirements that have come to the agency's attention since the regulation was finalized.

Importantly, however, entities with disclosure duties under these regulations are still required to make necessary disclosures (e.g., labeling the food "not processed to control *Salmonella*"). Moreover, subsequent entities in the distribution chain will continue to be subject to applicable requirements related to food adulteration in Federal and/or state and local laws and regulations (e.g., PCHF, PCAF, and the Retail Food Code).

III. Food Contact Substances Under FSVP

The FSVP regulation applies to the importation of "food" as defined in section 201(f) of the FFDCA, which includes FCS. 4/ FDA has decided, however, that it will exercise enforcement discretion for importers of FCS with respect to the FSVP regulation. The agency is taking this approach "because of certain characteristics related to the nature of [FCS], FDA's premarket review/oversight of [FCS], and the regulatory framework for such substances." FDA does not state an intent to engage in future rulemaking on this issue, instead explaining that it will consider revising this exercise of enforcement discretion if, for example, new information becomes available regarding safety concerns associated with FCS.

Further, FDA provides its position that FCS are not subject to the supply-chain program requirements in the PCHF regulation. The Guidance states: "Under that regulation, the supply-chain program requirements only apply to hazards requiring a supply-chain applied control, and FDA has determined that there are no hazards associated with [FCS] that are hazards requiring a supply-chain applied control under 21 C.F.R. 117.405(a)(1)."

IV. Certain Human Food By-Products for Use as Animal Food that Are Further Manufactured/Processed

The PCAF rule provides that human food facilities that are subject to and in compliance with the human food current Good Manufacturing Practice (cGMP) and FDA's other food safety requirements, and that do not further manufacture/process their human food by-products once the by-products have been separated for use as animal food, are only subject to a limited holding and distribution cGMP regulation. 5/ However, if the human food facility engages in any manufacturing/processing activities for the human food by-products for use as animal food, the facility becomes subject to the full PCAF regulation. Industry has raised concerns about application of the PCAF rule for facilities that perform certain low-risk manufacturing/processing activities before storing or transporting human food by-products for use as animal food.

In response to these concerns, FDA intends to exercise enforcement discretion regarding the PCAF requirements for human food facilities meeting the other limited holding and distribution cGMP requirements in §507.12, so long as the manufacturing/processing activities that are performed on the human food by-products for use as animal food are not performed to prevent or significantly

4/ 21 C.F.R. § 1.500.
5/ 21 C.F.R. § 507.12; *see also* 21 C.F.R. § 117.95.

minimize animal food hazards, do not introduce animal food hazards, and are limited to the following activities and circumstances:

- drying/dehydrating, evaporating, pressing, chopping, and similar activities to reduce weight, bulk, or volume, and/or
- mixing (*e.g.*, combining different vegetable culls and trimmings, combining juice and dairy by-products, stirring), centrifuging, and similar activities to combine ingredients or separate components (*e.g.*, water and solids).

The Guidance explains that FDA is providing enforcement discretion because it does not expect that these types of activities done for the purposes of reducing weight, bulk, or volume, and/or separating components, or combining ingredients will change the food safety profile of the animal food. The enforcement discretion does not extend to a human food facility that performs other manufacturing/processing activities on its human food by-products for use as animal food (e.g., drying to create a new commodity).

V. Certain Facilities That Are Similar to Farms

Numerous questions and concerns have been raised with FDA regarding the "farm" definition. FDA announces in the Guidance that it intends to initiate a rulemaking that could change the applicability of the preventive controls and cGMP requirements to some entities that conduct farm-related activities but that do not meet the current definition of a "farm" and thus are registered as "facilities." 6/ To provide sufficient time to pursue this rulemaking, FDA intends to exercise enforcement discretion with regard to the following types of operations and their compliance with cGMP and/or preventive controls requirements:

TABLE 1. Summary of Enforcement Policy with Regard to Human Food

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for human food preventive controls requirements?	Does enforcement discretion apply for human food CGMPs?
• Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility	• Yes	• No, for farm-related activities conducted on produce RACs. • Yes, for farm-related activities conducted on non-produce RACs.
• Facilities that would qualify as farms if they did not color RACs	• Yes	• No, for coloring produce RACs. • Yes, for coloring non-produce RACs.
• Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/ dehydrated to create a distinct commodity such as dried beans	• Yes	• No, for produce RACs. • Yes, for non-produce RACs.

6/ The agency notes that it does not anticipate that changes to the regulatory text would result in an entity that currently is a "farm" becoming subject to the PCHF or PCAF rules.

TABLE 2: Summary of Enforcement Policy with Regard to Animal Food

Description of facilities and activities conducted by the facilities	Does enforcement discretion apply for animal food preventive controls requirements?	Does enforcement discretion apply for animal food CGMPs?
• Facilities that would qualify as Secondary Activities Farms except for the ownership of the facility	• Yes	• Yes
• Facilities that would qualify as farms if they did not color RACs	• Yes	• Yes
• Facilities that would qualify as Secondary Activities Farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity such as dried beans	• Yes	• Yes
• Farm mixed-type facilities making silage food for animals	• N/A for small and very small businesses (because they are exempt from animal food preventive controls requirements). • Yes, for businesses that are not small or very small.	• Yes

Note that facilities that currently are exempt from the preventive controls or cGMP requirements will continue to be exempt from those requirements. For example, establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts are, and will continue to be, exempt from cGMPs. 7/

Regarding the exercise of enforcement discretion for facilities that would qualify as secondary activities farms except for the ownership of the facility, the enforcement discretion applies to any operation dedicated to harvesting, packing, and/or holding raw agricultural commodities (RACs). Accordingly, it also applies to facilities solely engaged in packing and/or holding activities on produce RACs and/or nut hulls and shells. Essentially, FDA's position in the Guidance is that if an operation is performing activities that would be exempt from the preventive controls and cGMP requirements were the operation a secondary activities farm, FDA will exercise enforcement discretion regarding compliance with cGMP and/or preventive controls requirements even if the operation is required to register as a "facility."

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We will continue to monitor developments related to FSMA implementation. Please contact us if you have any questions.

7/ 21 C.F.R. § 117.5(k)(v); 21 C.F.R. § 507.5(h)(2).