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FDA Extends Compliance Dates for Certain Provisions of FSMA Rules

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Food, Beverage, and Dietary Supplements and Animal Food and Drug

FDA has issued a final rule[1] extending and clarifying the compliance dates for certain provisions of four final rules recently issued as part of the agency's implementation of the FDA Food Safety Modernization Act ("FSMA").[2] According to the agency, the compliance dates are being extended to address concerns about the practicality of compliance with the specific regulatory provisions, to give FDA time to consider the regulatory text, and to better align the dates across the rules. Most of the date changes apply only to a narrow set of activities, and the major compliance dates for large companies remain the same. Significantly, however, the rule extends for two years the compliance dates for the written assurance provisions in the Human PC Rule, 21 C.F.R. §§ 117.136 and 117.137, and the parallel provisions in the Animal PC Rule in 21 C.F.R. §§ 507.36 and 507.37, which had been of great concern to many industry stakeholders, and FDA continues to consider the best approach to address stakeholders' feasibility concerns about these provisions.

FDA also released today the first five chapters of a multi-chapter draft guidance for industry on the PC Rule. Covington will publish a client alert on that draft guidance later this week.

Two-Year Extension for Written Assurance Requirement in Customer Provisions of 21 C.F.R. §§ 117.136 and 117.137 and Related Provisions

The most notable extension is a two year extension of the compliance dates for the "customer provisions" at 21 C.F.R. § 117.136(a)(2) through (4) and § 117.137 and related provisions (*e.g.*, recordkeeping requirements) and the parallel provisions in the Animal PC Rule in 21 C.F.R. §§ 507.36(a)(2) through (4) and 507.37. Under those provisions, after a manufacturer/processor identifies a hazard requiring a preventive control, does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard, the manufacturer/processor is not required to implement a preventive control for the identified hazard if the manufacturer/processor: (1) discloses to its customers that the food is "not processed to control [identified hazard]" (which FDA refers to as the "disclosure statement provisions"); (2) obtains

[1] The pre-publication format of the rule is available here. It will formally publish in the Federal Register tomorrow.

[2] These are the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Final Rule (the "Human PC Rule," codified in FDA's regulations at Part 117), the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals Final Rule (the "Animal PC Rule," codified in FDA's regulations at Part 507), the Foreign Supplier Verification Programs ("FSVP") for Importers of Food for Humans and Animals Final Rule, and the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Final Rule.

written assurance from the customer that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements (which FDA refers to as the "written assurance provisions"); and (3) complies with provisions relating to accountability for written assurances.

In response to serious concerns from industry stakeholders that the written assurance provisions would require the development and tracking of many hundreds or thousands of documents by a single entity, which burden FDA does not appear to have accounted for or intended, the agency states in today's rule that it believes the requirement for written assurance "significantly exceeds the current practices of even the largest facilities." Thus, the agency feels that it "may not be feasible" for those facilities to comply by September 19, 2016 (the compliance date of the Human PC Rule for businesses that are neither small nor very small) and is extending for two years for all business types the compliance dates for the written assurance requirements and related provisions "while FDA considers the best approach to address feasibility concerns." FDA is correspondingly extending the compliance dates for the written assurance provisions of the Animal PC Rule.

The final rule provides a table summarizing the revised compliance dates for the written assurance provisions. Small businesses subject to Part 117 will have until September 18, 2019 to comply. For all other businesses, the compliance date for Section 117.136(a)(2)(ii), (3)(ii), and (4)(ii) has been extended from September 19, 2016 to September 19, 2018. The compliance dates are also extended by two years for the written assurance requirements in the customer provisions in Part 507, under the FSVP regulation in Section 1.507, and under the produce safety regulation in Section 112.2(b)(3).

Notably, FDA did not delay the compliance date for the disclosure statement provisions, as the agency believes it remains appropriate for an entity earlier in the distribution chain to disclose that a hazard has not been controlled and to rely on a subsequent entity to control a hazard in human or animal food. FDA will further address the disclosure statement provisions in guidance.

Other Compliance Dates Extended

FDA is also extending the compliance dates for certain provisions in or activities under the four final rules. These extensions include:

- A sixteen-month extension for compliance with Parts 117 and 507 for facilities solely engaged in packing and/or holding activities conducted on raw agricultural commodities (RACs) that are produce and/or nut hulls and shells and for certain facilities that would qualify as secondary activities farms except for the ownership of the facility;
- A sixteen-month extension for compliance with Part 117 for certain facilities that color RACs;
- A sixteen-month extension for compliance with Part 507 for facilities solely engaged in the ginning of cotton;
- A two-year extension for compliance with the FSVP regulation for importation of food contact substances; and
- Extending the compliance date for certain facilities producing Grade "A" milk and milk products covered by the National Conference on Interstate Milk Shipments (NCIMS) under the Pasteurized Milk Ordinance (PMO) to comply with the CGMP requirements of Part 117 to September 17, 2018.

Covington continues to monitor closely FDA's implementation of FSMA and will keep its clients apprised of significant developments.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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