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# FDA Releases Draft Guidance regarding Current Good Manufacturing Practice Requirements for Animal Food

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Animal Food and Drug

Earlier this week, the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) published Draft Guidance for Industry #235, "Current Good Manufacturing Practice Requirements for Food for Animals," as part of the agency's implementation of the Food Safety Modernization Act (FSMA). The draft guidance contains information designed to help animal food facilities determine whether they need to comply with the animal food current good manufacturing practice (CGMP) requirements in 21 C.F.R. part 507[1] and, if so, how. Unlike the draft guidance FDA also issued this week on CGMP requirements for human food, this animal food CGMP guidance is not intended to be part of a multi-chapter guidance, but is a stand-alone document. There will, however, be future guidances on other provisions of part 507, including hazard analysis and preventive controls for animal food. This alert highlights key aspects of the draft guidance that will be of interest to industry stakeholders.

## Scope of CGMP Requirements

An establishment required to register as a food facility under section 415 of the Federal Food, Drug, and Cosmetic Act because it manufactures, processes, packs, or holds animal food (including animal food ingredients) is subject to the CGMP requirements, unless an exemption applies. The draft guidance identifies two such exceptions: (1) establishments that are not required to register under section 415,[2] and (2) facilities solely engaged in three enumerated types of activities.[3] For purposes of determining whether a facility is "solely engaged" in one of those activities, the draft guidance notes that a facility may consist of one or more contiguous structures, so if a single facility conducts different types of operations in separate physical structures, it is not "solely engaged" in any of those operations.

[1] The final rule that added Part 507 to FDA's regulations was published on September 17, 2015, *see* 80 Fed. Reg. 56170 (Sept. 17, 2015), and was the subject of a separate Covington Alert.

[2] 21 C.F.R. § 507.5(a).

[3] 21 C.F.R. § 507.5(h) (providing that the CGMP requirements do not apply to establishments "solely engaged in the holding and/or transportation of one or more raw agricultural commodities; . . . hulling, shelling, drying, packing, and/or holding nut and hulls (without manufacturing/processing, such as grinding shells or roasting nuts); . . . [or] ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed).").

The draft guidance additionally provides that under part 507, a combined human and animal food facility may elect whether to follow the human food CGMPs found in 21 C.F.R. part 117 for both human and animal food, or to follow part 117 for human food and part 507 for animal food.[4] The draft guidance recommends that to make that determination, facilities consider the nature of their operations, including whether human and animal food operations involve the same employees, production lines, or holding areas.

The draft guidance also advises that human food by-products for use as animal food are exempt from all CGMPs except for limited requirements relating to holding and distribution.[5] If an animal food facility is subject to specific CGMPs other than the general animal food CGMPs (for example, CGMPs for low acid canned food or medicated feed), it must comply with those CGMPs in addition to the part 507 CGMPs.

## Discussion of Specific CGMP Requirements

The draft guidance describes and makes recommendations regarding specific CGMPs relating to training and qualifications (part 507, subpart A); recordkeeping (part 507, subpart F); and the general CGMP requirements for animal food, including with respect to personnel, plant and grounds, plant conformation, protection of bulk feed stored outdoors, sanitation, water supply, equipment, operations, and holding and distribution (part 507, subpart B). The discussion is detailed, and we recommend that you review the draft guidance as you develop your animal food CGMP compliance program. As a general matter, the draft guidance notes that the CGMP requirements in part 507 were designed to be flexible where appropriate to allow them to be applied in various animal food production settings in a diverse industry.

## Comment Period

Although FDA accepts public comments on guidance documents at any time, you should submit comments on the draft guidance **by November 23, 2016**, to ensure that the agency considers those comments before it issues the final version of the guidance.

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

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[4] 21 C.F.R. § 507.1(d).

[5] 21 C.F.R. §§ 117.95, 507.12, & 507.28. Human food by-products for use as animal food are the subject of a separate FDA draft guidance issued this week. *See* FDA, Draft Guidance for Industry #239, *Human Food By-Products for Use as Animal Food* (Aug. 2016). That draft guidance is discussed in a separate Covington Alert.

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


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