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**MEMORANDUM**

September 30, 2016

**TO:** Agricultural & Food Law Consortium

**RE:** FSMA Animal Food Rule – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls

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On September 10, 2015, the federal Food and Drug Administration (“FDA”) released a major final rule to implement the Food Safety Modernization Act (“FSMA”): Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (the “Final Rule”), 80 Fed. Reg. 56,170 (Sept. 17, 2015).

<sup>1</sup> I would like to acknowledge and extend special thanks to Joldya Swaim, a principal at OFW Law, and Barbara Masters, DVM, a former senior policy advisor at OFW Law, who assisted in drafting portions of this memorandum.

This memorandum summarizes the major components of the Final Rule as well as practical tips for feed industry professionals and legal practitioners based on FDA guidance and related training programs.

## I. EXECUTIVE SUMMARY

The Final Rule is a culmination of multiple years of rulemaking.<sup>2</sup> Section 103 of FSMA added a new section 418 to the Federal Food, Drugs, and Cosmetics Act (“FD&C Act”) that required FDA to promulgate regulations that require animal food facilities that are required to be registered under section 415 of the FD&C Act<sup>3</sup> to establish and implement a food safety system that includes hazard analysis and risk-based preventive controls. After significant input from industry stakeholders during the rulemaking process, FDA has incorporated many of these suggestions into the Final Rule.

The major provisions of the Final Rule include:

- **Current Good Manufacturing Practices (“CGMPs”)** – Under Subpart B of the Final Rule, *all* registered animal food facilities (with a few exceptions – *see* Section III) will need to comply with CGMPs that address food safety concerns associated with the manufacturing, processing, packing, and holding of food for animals.
- **Hazard Analysis and Risk-Based Preventive Controls** – Under Subpart C of the Final Rule, *some* domestic and foreign animal food facilities will need to establish and implement hazard analysis and risk-based preventive controls for animal food. Registered facilities subject to Subpart C must maintain a written food safety plan, perform a hazard analysis, and institute preventive controls to mitigate the identified hazards. Additionally, registered animal food facilities will be required to monitor their preventive controls, conduct verification activities to ensure the preventive controls are effective, take appropriate corrective actions, and maintain records documenting these actions.
- **Supply-Chain Controls** – Under Subpart E of the Final Rule, animal food

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<sup>2</sup> On October 29, 2013, FDA released a proposed animal feed rule that outlined many of the provisions included in the Final Rule. *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls; Proposed Rule, 78 Fed. Reg. 64,736 (Oct. 29, 2013) (the “Proposed Rule”). FDA also introduced revised provisions for comments in a supplemental proposed rule on Sept. 29, 2014. *See* Supplemental Notice of Proposed Rulemaking: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls; Proposed Rule, 79 Fed. Reg. 58,476 (Sept. 29, 2014) (the “Supplemental Proposed Rule”).

<sup>3</sup> Pursuant to the Bioterrorism Act of 2002, Congress directed FDA to establish a registry of all facilities that manufacture, processes, packs, or holds human or animal food for consumption in the United States. *See* 21 U.S.C. § 350d. Farms are generally not required to register as food facilities so long as all of the products they handle are consumed on the farm. Please see 21 C.F.R. § 1.227 for a thorough understanding of facility registration requirements.

manufacturing/processing facilities will be required to have a risk-based supply chain program for those raw materials and other ingredients for which the facility has identified a hazard requiring a supply-chain-applied control. If the animal food facility controls the hazard using preventive controls, or follows specific requirements when they rely on a customer to control the identified hazards, they do not need to have a supply-chain program for that hazard.

Animal food facilities will be responsible for ensuring that raw materials and other ingredients that are controlled by a supply-chain program are received only from approved suppliers.<sup>4</sup>

Preventive controls will not be required at facilities when an identified hazard is controlled elsewhere in the distribution chain (*e.g.*, a customer or other processor). The facility will have to disclose that the food is “not processed to control [identified hazard]” and will also have to obtain a written assurance from their customer in regards to actions that the customer agrees to take.

- **Vertically-Integrated Farming Operations** – Feed mills associated with *fully* vertically-integrated farming operations (*i.e.*, farms where the feed mill, animals, land, and establishment are all owned by the same entity) are considered “farms” and are not subject to the CGMPs or preventive controls. This is the case even in instances where the feed mill is not located on the same property as the animals.

However, in the instance where a feed mill is owned by an entity that contracts out the task of raising the entity’s livestock or poultry, the feed mill is not considered to be part of a “farm.” FDA reasons that these feed mills cannot be considered part of a farm because they manufacture feed for animals that are not managed by the feed mill’s owner. As such, feed mills that serve contract livestock and poultry farmers are subject to the Final Rule’s CGMP and preventive controls requirements.

Fearing that the farm exemption leaves significant gaps in the protection of human and animal health, FDA has indicated that the agency will propose a subsequent rulemaking that would apply CGMP and preventive control requirements to some feed mills that service fully vertically-integrated farming operations.

- **Staggered Compliance Timelines** – The deadlines for compliance with the CGMPs and preventive controls will be staggered. Furthermore, “small” and “very small” businesses will have additional time to comply with the provisions of the Final Rule. Section VII discusses the compliance timelines in further detail.

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<sup>4</sup> Raw materials may be received from an unapproved supplier on a temporary basis if the raw materials are subject to verification prior to receipt.

## II. NOTABLE DEFINITIONS AND CONCEPTS

### a. Hazard Requiring a Preventive Control

A key consideration for any facility subject to the Final Rule is whether any of the food products manufactured, processed, packed, or held by the facility contains a “hazard requiring a preventive control.” FDA defines the term as:

*a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records), as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility’s food safety system.”<sup>5</sup>*

If a facility handles a product with a hazard requiring a preventive control, then it must develop a written food safety plan and implement preventive controls. However, if a facility’s hazard analysis does not identify any hazards requiring a preventive control, it can forego developing a written food safety plan and implementing preventive controls. This distinction accomplishes FDA’s goal of a tiered approach to regulating food safety matters in plants. Due to the relative hazards and risks, some livestock and poultry feed manufacturers may not handle products requiring preventive controls, whereas most pet food manufacturers will be required to implement preventive controls.

### b. Supplier Controls

The rule added a definition for “supply-chain-applied control.” The term is defined as “a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.” The Final Rule changed the phrase “supplier-program” to “supply-chain program” and moved the requirements to a stand alone section (Subpart E). The Final Rule increases flexibility for the supply-chain programs and adjusted the compliance dates for these provisions such that a food facility will not have to comply with these provisions prior to the time it is required to comply with the preventive controls for animal food rule or the produce safety rule.

### c. Small and Very Small Businesses

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<sup>5</sup> See 21 C.F.R. § 507.3.

The Final Rule provides accommodations for smaller businesses in the form of modified preventive control requirements (detailed in Section VII). In 21 C.F.R. § 507.3, FDA defines the terms as such:

- **Small Business** - *a business employing fewer than 500 full-time equivalent employees (this is viewed on a business-wide scale, and is not limited to the number of employees working in animal food)*
- **Very small business** - *a business (including any subsidiaries and affiliates) averaging less than \$2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)*

#### **d. Definition of “Farm” & Implications for Vertically-Integrated Operations**

Farms are not required to register as food facilities and are not required to comply with the Final Rule. Taking modern farm operations into consideration, FDA amended its definition of a “farm,” for the purposes of the FD&C Act, in 21 C.F.R. § 1.227. Specifically, the agency developed two sub-categories of farms: primary production farms and secondary activities farms.

- **Primary Production Farm** – FDA defines a primary production farm as an operation under common management (“under one management”)<sup>6</sup> in one general, but not necessarily contiguous, location devoted to the growing of crops, harvesting of crops, the raising of animals (and seafood), or any combination of these activities.
- **Secondary Activities Farm** – Under FDA’s revised definition, a secondary activities farm is located separately from a primary production farm and is used, in the animal food context, mostly for packing and holding of grain.

The revision of the “farm” definition has implications regarding the jurisdiction of the Final Rule. For example, suppose Farm X has a feed mill that exclusively services Farm X’s beef cattle herd. Farm X purchases some of the grain that it processes at its feed mill from Farm Y. Under FDA’s revised definitions, Farm X would not be subject to the Final Rule even though it processes grain that did not originate on the farm.

In contrast, if a poultry integrator operates a feed mill to service its contract growers; that feed mill is subject to CGMPs and preventive controls requirements because the contract growers and the poultry integrator do not share common management.

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<sup>6</sup> This replaces the term “under one ownership” that was used in the original definition of “farm” to better represent and include the farms whose ownership is by multiple growers, food aggregators, etc., but for which the control of the business is “under one management.”

**e. Human Food By-Products (§ 507.12 “Applicability of this Part to the Holding and Distribution Human Food By-Products for Use as Animal Food”)**

Animal food facilities that are already in compliance with human food safety requirements (*e.g.*, brewers, distillers) do not need to implement additional CGMPs or preventive controls when supplying a by-product (*e.g.*, wet spent grains, liquid whey, or fruit or vegetable peels) for animal food, except to prevent physical or chemical contamination when holding or distributing the by-product. The requirement to prevent contamination applies regardless of whether the facility donates or sells by-products as animal food.

In contrast, further processing a human food by-product for use as animal food (*e.g.*, drying, pelleting, and heat treatment) requires entities to process the by-product in compliance with CGMPs and ensure that hazards are not introduced to animal food. In this circumstance, the facility may choose to either comply with the Human Food Rule or the Animal Food Rule. It is important to note that § 507.12 does **not** apply to “human food by-products when contamination or other adulteration has occurred that is materially related to food safety”. If a human food by-product poses a food safety risk, requests for approval to use the by-product as animal food should be made to FDA following Compliance Policy Guidance Numbers (CPG) Sec. [675.100](#) or [625.200](#). For example, for dry milk powder that has tested positive for *Salmonella* to be diverted to animal food, a request based on one of the CPGs would need to be made to FDA.

### **III. CURRENT GOOD MANUFACTURING PRACTICES**

The Final Rule’s CGMP requirements serve as the baseline safety and sanitation standards for facilities that are subject to the Final Rule. With a few exceptions (detailed below), all registered facilities will be required to comply with the CGMP requirements, whereas, not all facilities will be required to implement preventive controls.

In general, a facility is required to implement preventive controls if the facility has identified a “known or reasonably foreseeable hazard” that requires a preventive control. Properly implemented CGMPs may serve as a prerequisite program that will decrease the likelihood that a known or reasonably foreseeable hazard will occur in the absence of a preventive control.

Full compliance with the CGMP provisions should reduce the likelihood that animal food will be considered adulterated because it was manufactured/processed, packed, or held under insanitary conditions. An animal food that is produced under insanitary conditions is adulterated, whether or not it contains a harmful substance. Failure to comply with CGMPs may result in an animal food being deemed adulterated.

**a. Applicability**

**Exemptions:** A facility is exempt from the CGMP requirements if it is not required to register under section 415 of the FD&C Act. Examples of these facilities include: (1) farms; (2) facilities that are regulated exclusively, throughout the entire facility, by the U.S Department of Agriculture (meat, poultry, egg products); (3) retail food establishments; (4) restaurants, which includes pet shelters, kennels, and veterinary facilities that provide food to animals; (5) foreign facilities if the food undergoes further manufacturing/processing by another facility outside the United States.

Facilities *solely* engaged in the following activities are not subject to CGMP requirements: (1) holding and/or transportation of one more raw agricultural commodities (*e.g.*, grain elevators); (2) hulling, shelling, drying, packing and/or holding nuts and huts (without processing, such as grinding shells or roasting nuts); and (3) ginning cotton (without further processing, such as oil extraction). A facility is only “solely” engaged in these activities if no other manufacturing/processing activities are conducted at the facility.

**Modified Requirements:** Facilities that manufacture, process, pack or hold food for both humans and animals may choose to comply with both human and animal food CGMPs, or they may choose to comply solely with the human food CGMPs. In deciding whether to adopt both human and animal food CGMPs, a facility should consider their particular operation. FDA recommends that facilities that share common employees, production lines, and holding areas for human and animal food should adopt the human food CGMPs (21 CFR Part 117) for both human and animal food.

If a human food facility generates by-products that are used in animal food (*e.g.*, wheat middlings, grain hulls, or human foods that do not meet quality requirements – chips, cookies, bread), then it may only be subject to CGMPs for holding and distribution of animal food. Such facilities are not eligible for the modified requirements if they further process these products.

**Supplemental CGMPs:** Facilities that are subject to special CGMP requirements, such as low acid canned food and medicated feeds, must comply with the animal food CGMPs and the special CGMP requirements. In instances where there is overlap between the animal food CGMPs and the special CGMPs, the facility must comply with the more specific of the two requirements.

## **b. Training and Qualification Requirements**

### **i. Management Responsibilities (21 C.F.R. § 507.4(a)(1) and 507.4(c))**

An establishment’s management is required to ensure that all individuals (including contractors) who manufacture, process, pack, or hold animal food are qualified to perform their tasks. FDA suggests that determining whether an individual is qualified depends on whether they have the necessary training, experience, and competency to carry out their assigned duties.

Furthermore, management must assign supervisors to ensure that plant personnel are carrying out their tasks properly. FDA suggests this supervision requirement can be met by making clear assignments of responsibility through job descriptions, organizational charts, or discussing these responsibilities with supervisory personnel.

**ii. Qualifications and training of individuals who manufacture, process, pack or hold animal food (21 C.F.R. § 507.4(b))**

**Supervisors:** Individuals who supervise or perform manufacturing, processing, packing, or holding activities for animal food must: (1) be a qualified individual and (2) receive training in the principles of animal food hygiene and safety. These requirements apply even if the individual only works on a temporary or seasonal basis.

**“Qualified Individual”:** An individual is qualified if they have the necessary education, training, or experience to perform their task. Non-employees that enter animal food areas in plants, such as electricians, janitors, or technicians, must be qualified to perform their work in an animal food facility.

**Training:** Training in the principles of animal food hygiene and safety must include information on the importance of employee health and personal hygiene, but training requirements will depend on the type of facility and the required duties. FDA suggests that training should take into account the range of duties that an employee will have responsibility for. Training can be provided by in-plant instruction, classroom training, videos, or online programs. FDA has not established requirements regarding frequency of training but it should be adequate and should include refresher training from time to time.

**i. Training recordkeeping (21 C.F.R. § 507.4(d))**

Facilities are required to keep records to document their training on animal food hygiene and safety. FDA suggests that facilities can develop training records in convenient forms, such as: (1) training checklists for new employees; (2) sign in sheets for specific trainings; or (3) computerized training records.

Training records are subject to FSMA’s recordkeeping requirements under Subpart F. These records must be made promptly available to inspectors for review and copying upon written or oral request. The training records should identify the facility, the date of the training activity, and the signature or initials of the person performing the training activity. FDA suggests that such records should also include: (1) a list of the persons trained; (2) a description of the content of the training; and (3) the name and qualifications of the trainer.

All training records must be retained for at least two years after the date they were prepared. Records of required training in animal food hygiene and safety for employees should be kept for at least two years after the trained individual stops working for the facility.

### c. Requirements

Under subpart B, managers of registered facilities are required to adopt CGMPs for the following aspects of their animal food operation:

#### 1. Personnel (§ 507.14)

Management of a facility must take reasonable measures and precautions to ensure that all individuals (employees, contractors, visitors) working in direct contact with animal food, animal food-contact surfaces, and animal food-packaging materials conform to hygienic practices. Basic hygiene principles include: maintaining adequate personal cleanliness, washing hands as necessary, removing or securing jewelry and other objects, and storing clothing in appropriate places. FDA notes that cleanliness standards will vary by facility. For example, employees in livestock feed mills could have dusty clothes; however, they should not be around livestock feed manufacturing if their clothes are covered in oil, grease, or excessive dirt. In contrast, a pet food employee may need dedicated footwear and protective clothing.

Employees should be provided adequate handwashing facilities. FDA notes that handwashing facility requirements will vary by the type of animal food produced and duties performed. In facilities that produce food where undesirable microorganisms are a concern, handwashing should occur when individuals enter the food production area after they handle or touch anything other than food or food contact surfaces (floor, door handle, hoses), and before they handled any finished animal food that has been subjected to a “kill step.”

Personal belongings and tools, including cell phones, pocket knives, jewelry, and sunglasses, should be secured such that they do not present a risk of falling into food or they should be stored in an area separate from where food is produced or utensils and equipment are stored.

#### 2. Plant and grounds (§ 507.17)

**Grounds:** The grounds around a plant should be maintained in a way that they do not contribute to contamination of food. This extends to grounds owned or leased by the establishment that are close enough to impact plant operations. The grounds must be maintained by properly storing equipment, removing trash, and cutting weeds or grass in the immediate vicinity to the plant that could attract, harbor, or serve as a breeding place for pests. Furthermore, driveways, yards, and parking areas should be maintained so they are not a source of contamination for exposed animal feed. Drainage should also be adequate to prevent contamination.

Waste, including sewage, other liquid waste, and processing waste, should be properly handled to prevent contamination. Portable toilets should be located away from animal food storage. Processing waste should be stored in appropriate receptacles and removed from the site on a regular basis.

**Plant:** A plant must be suitable in size, construction, and design to facilitate cleaning, maintenance, and pest control to reduce the potential for contamination of animal food, animal food-contact surfaces, and animal food-packaging materials. FDA does not expect facilities to be redesigned or reconstructed to meet this requirement; however, some facilities may have to undertake maintenance, repair, retrofitting or other changes.

Facilities should have adequate space between equipment, walls, and stored material to allow for cleaning, maintenance, and other employee duties. This area should be cleaned to prevent pests and food contamination. Furthermore, the plant must be constructed in a way that drip or condensate from fixtures, ducts, and pipes are not a source of contamination. FDA suggests that, where possible, pipes and ducts should not be located over animal food-contact surfaces. Drip pans and pipe insulation can be used to prevent contamination.

**Ventilation:** Ventilation should be adequate to minimize vapors and fumes that could contaminate animal food. Ventilation used to reduce dust or lower heat should be done in a way that minimizes potential contamination. Ventilation can be either mechanical (fans) or natural (open window) so long as it would not contribute to product contamination. Open doors or windows should have screens to minimize pests.

**Lighting:** Lighting should be provided in hand-washing areas, toilet rooms, and areas where animal food is handled. Lighting should be bright enough to allow employees to conduct their activities. Lightbulbs, fixtures, skylights, or other glass items suspended over exposed animal food in any preparation area should be shatter resistant to protect against contamination of animal food.

**Bulk Outdoor Storage:** If a facility stores bulk ingredients outdoors, it must protect against contamination by any effective means. Protective coverings, such as tarps, should be used where necessary and appropriate. Furthermore, the area around the outdoor storage should be controlled to eliminate pest harborage. This includes draining water away from outdoor storage, removing trash and old, decomposing food. Outdoor storage should be inspected on a regular basis for pest infestation and food contamination and spoilage. Bait stations can be employed to eliminate pests so long as they do not serve as a potential source of contamination for the food.

### **3. Sanitation (§ 507.19)**

A facility's buildings, structures, and fixtures, and other physical features of a plant must be kept clean and in good repair to prevent animal food from becoming adulterated.

**Surfaces:** Surfaces (both food-contact and non-contact) of utensils and equipment must be cleaned and maintained to protect against contamination of animal food, food-contact surfaces, or packaging materials. Utensils (e.g., buckets, shovels, scoops, knives) should be maintained so that pieces do not break off into animal food. Cleaning procedures will vary depending on the

type of product being manufactured. When necessary, equipment should be disassembled for thorough cleaning. FDA suggests this should be done in accordance with the equipment manufacturer's instructions.

Sanitation procedures will vary by the type of food product produced. In pet food facilities, pathogens are a concern. Accordingly, wet sanitation should be used on food-contact surfaces. When wet sanitation is used, surfaces should be allowed to dry after sanitation. If pathogens are a concern, food-contact surfaces should be sanitized before use and after any interruption wherein a surface could have become contamination. In contrast, livestock feed mills often employ dry cleaning methods, such as scraping, sweeping, vacuuming, flushing, or sequencing.

**Cleaning Compounds:** Cleaning compounds and sanitizing agents should be adequate and safe. FDA recommends reading the labels of these products to determine their proper use. The products should be used in accordance with the label's instructions.

**Utensil and Equipment Storage:** Utensils and equipment must be stored as necessary to protect against contamination of animal food, food-contact surfaces, and packaging materials. FDA recommends storing utensils and equipment away from raw materials or ingredients, under protective covering, inverted, or in another way that protects against contamination.

**Toxic Materials:** The only toxic materials that can be stored in the area of a plant where animal food is manufactured, processed, or exposed are those materials needed for cleaning and sanitizing, plant and equipment maintenance and operation, laboratory testing procedures, and use in the plant's operations. FDA recommends leaving these products in their original containers with labeling intact. If they are transferred to other containers, the container should identify the contents and instructions for proper use should be readily available. These products should be stored according to manufacturer instructions. Other toxic materials, such as fertilizer or pesticides, should be stored separately from the animal food area of an establishment.

**Pests:** Facilities must take effective measures to exclude pests. FDA recommends developing a comprehensive pest control plan that includes regular monitoring for the presence of pests and measures to exclude pests (*e.g.*, screens, keeping doors and windows secured, caulking holes). Pesticides may be used only under precautions and restrictions that will protect against the contamination of animal food, food-contact surfaces, and packaging materials.

**Trash:** Trash must be conveyed, stored, and disposed of in a way that protects against the contamination of animal food, food-contact surfaces, and food-packaging materials, water supplies, ground surfaces, and minimizes the potential to attract or harbor pests.

#### **4. Water supply and plumbing (§ 507.20)**

**Water Source:** Water used by the plant must be adequate for the operations, meaning that the

water supply must be sufficient for its intended purpose, in keeping with good public health practices. The water should be free of contaminants and meet the water quality standards required for the product; the water source should not adulterate the food. Running water at a suitable temperature and pressure must be provided in all areas where it is required for the manufacturing, processing, packing, or holding of animal food, for the cleaning of equipment, utensils, and packaging materials, and for hand-washing facilities. Water temperature and pressure requirement may vary depending on the activity requiring water.

**Plumbing:** Plumbing must be designed, installed, and maintained to carry adequate quantities of water and sewage. The plumbing must not be a source of contamination to animal food, water supplies, or equipment and utensils. Where possible, plumbing should not be installed above animal food or food-contact surfaces. Floor drainage should also be adequate to prevent potential contamination.

**Toilets and Hand-washing Stations:** Each plant must provide employees with adequate, readily accessible toilet facilities. These facilities can be located inside the plant or in an adjacent building. Furthermore, each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a potential source of contamination of animal foods, food-contact surfaces, or packaging materials. These hand-washing facilities are often located near toilets, but should also be located in other convenient areas of the plant if undesirable microorganisms are a concern for the animal food product.

## 5. Equipment and utensils (§ 507.22)

**Cleaning:** All plant equipment and utensils must be designed and constructed to be adequately cleanable. The equipment and utensils must also be properly maintained, regardless of whether they come into contact with animal food. All equipment should be able to withstand regular cleaning procedures and should be replaced or repaired when they can no longer be cleaned. Care should be taken to ensure that equipment and utensils do not adulterate animal food with non-food grade lubricants, fuel, metal fragments, contaminated water, or any other contaminants. Food grade lubricants should be used on equipment and utensils that come into contact with animal food. Metal should not be corroded or produce shavings or have pieces that could easily break off and become physical contaminants.

**Containers:** Animal food containers should be made of materials that withstand the environment of their use, the action of animal food, and the action of cleaning compounds and sanitizing agents without breaking, chipping, or cracking. Furthermore, food-contact surfaces must be made of nontoxic materials that are safe for use with the food product. They should be maintained to prevent contamination.

**Freezers and Cold Storage:** Each freezer and cold storage compartment used to hold animal food must be fitted with an accurate temperature-measuring device. This is necessary because temperature may vary by compartment.

**Instruments and Controls:** If a plant used instruments and controls to measure, regulate, or record temperatures, pH, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in animal food, these instruments or controls must be accurate, precise, adequately maintained, and adequate in number for their designated uses. This technology should be maintained and operated in accordance with manufacturer's instructions.

## 6. Plant operations (§ 507.25)

**Management:** A facility's management is responsible for implementing the CGMPs. FDA recommends that management develop and implement a system of oversight and checks (e.g., standard operating procedures) that ensure the physical facilities and individuals comply with CGMPs. Plant management is responsible for ensuring that raw materials, other ingredients, rework, and finished animal food is accurately identified to prevent commingling, substitution, or incorrect formulations that could result in adulteration. Management is also responsible for ensuring that packaging material is safe, appropriate for the food product, and not a source of contamination.

Plant management is responsible for ensuring that adequate precautions are taken to prevent the plant's operations from contributing to contamination. FDA recommends conducting regular checks to ensure policies and procedures are followed and effective. Management can also direct personnel to verify that equipment and automated systems are performing correctly.

Management must also ensure proper testing procedures are used when necessary to identify sanitation failures and contamination. This could include testing a line to ensure sanitation or testing food if a failure is suspected. If food is adulterated, management is responsible for ensuring it is properly disposed of or treated to eliminate the adulteration. Finally, management must ensure that food and packaging do not become contaminated with undesirable microorganisms.

**Raw Materials and Other Ingredients:** Raw materials and other ingredients must be examined to ensure they are suitable for animal food. An examination may include: (1) reviewing specifications, guarantees, or other information received by the facility; (2) performing a visual check of the food or its packaging; (3) sampling and testing; and/or (4) checking incoming temperatures for refrigerated or frozen ingredients.

Shipping containers and bulk vehicles must be examined upon receipt to determine if its condition could have contributed to contamination (e.g., rodent chewing). Furthermore, upon receipt, raw materials may need to be cleaned to minimize contamination.

Raw materials, rework, and other ingredients must be stored in containers that protect against contamination and deterioration. They must be held under conditions that will minimize the potential for growth of undesirable microorganisms and prevent adulteration. If raw materials are susceptible to mycotoxin or other natural toxins, they must be used in a way that does not result in illness to animals or humans. In evaluating these ingredients, the geographic source,

seasonal growing conditions, and test results should be used to decide how to use the ingredient to produce a safe food.

**Requirements for manufacturing, processing, packing, and holding operations:** During animal food operations, food must be maintained under conditions that will minimize the potential for growth of undesirable microorganisms or adulteration. Depending on the type of animal food, it may be necessary to perform operations in controlled humidity or temperature environments to minimize microorganism growth.

Treatment actions (e.g., heat treating, refrigeration) should be appropriate for the type of animal food and generally known (e.g., scientific authority) to significantly minimize or prevent the growth of undesirable microorganisms. Rework product should be easily identified as such and not commingled with finished product.

## **7. Holding and distribution (§ 507.27).**

**Holding conditions for animal food held for distribution:** Animal food held for distribution must be stored under conditions that will protect against contamination and minimize deterioration. Deterioration can present an animal health hazard if food become unpalatable and an animal does not consume adequate rations.

Storage containers must be designed and constructed out of appropriate materials, cleaned as necessary, and maintained to protect against contamination. The type of animal food stored, the frequency of reuse, and whether containers are transferred to other sites should be considered. Animal food stored for distribution should be stored to prevent contamination with trash and other contaminants. FDA recommends proper labeling to ensure there is not confusion between containers.

**Labeling:** When applicable, animal food ready for distribution must have labeling that contains information and instructions for safely using the product for the intended animal species. FDA's animal food labeling instructions are found in 21 CFR Part 501. Animal food is also subject to state laws that include information about directions for use and warnings or other caution statements.

**Shipping Containers and Bulk Vehicles:** When the facility is responsible for transporting feed or arranges shipment with a third-party, the shipping containers and bulk vehicles must be examined prior to use to prevent contamination. If the facility is the shipper, FDA expects personnel involving unloading the product to be aware of the condition of the shipping container or vehicle and consider whether its condition would lead to contamination. Depending on the circumstances, this may involve a visual examination. If a visual examination is not practical, the facility should know what the shipping container or vehicle had previously been used for and whether the container needs to be cleaned prior to use. However, containers do not always have to be cleaned prior to use.

The CGMPs do not require the facility to examine shipping containers or bulk vehicles when the customer arranges for transportation. However, if the facility has personnel onsite and available, FDA recommends inspecting the customer's vehicle or shipping containers to ensure there is no risk of contamination.

FDA has issued a Sanitary Transportation rule, which establishes requirements for shippers of food to use sanitary practices. Animal food operations engaged in transport must comply with these rules.

**Animal Food Returned from Distribution:** Animal food returned from distribution must be assessed for food safety to determine the proper disposition. Evaluation factors include: (1) the type of animal food; (2) the reason the animal food was returned; and (3) whether integrity of the animal food was maintained after it left the plant. Returned animal food must be identified and segregated until assessed. FDA recommends using separately labeled bins to store this food.

#### IV. PREVENTIVE CONTROLS

Subpart C of the Final Rule requires most registered facilities to conduct a hazard analysis to determine whether any product presents a known or reasonably foreseeable hazard that requires a preventive control. If such a hazard is identified, the facility must develop a written food safety plan and implement risk-based preventive controls.

##### a. Applicability

All registered animal food facilities are required to comply with the Final Rule's hazard analysis and preventive controls unless an exception applies. These exemptions are listed and explained in the table below.

<b>Who or What Is Exempt From the Requirements for Hazard Analysis and Risk-Based Preventive Controls</b>	<b>Notes</b>
<p>“Qualified Facility” as defined by FSMA:</p> <ol style="list-style-type: none"> <li>1. Business with avg. annual sales of &lt; \$500,000 and at least half the sales to consumers or local retailers or restaurants (within the same state or within 275 miles); or</li> <li>2. “Very Small Business,” defined as an entity (including subsidiaries and affiliates) averaging less than \$2,500,000 per year during the prior 3-year period in sales of animal food plus the market value of animal food</li> </ol>	<p>Modified requirements apply – <i>i.e.</i>, a qualified facility is required to:</p> <ul style="list-style-type: none"> <li>• Notify FDA about its qualified status and either:                             <ul style="list-style-type: none"> <li>○ Notify FDA that it is addressing hazards through preventive controls and monitoring; or</li> <li>○ Notify FDA that it complies with applicable non-Federal food safety regulations, and notify consumers of the name and complete business address of the facility where the</li> </ul> </li> </ul>

manufactured, processed, packed, or held without sale ( <i>e.g.</i> , held for a fee or supplied to a farm without sale)	<p>animal food was manufactured or processed.</p> <ul style="list-style-type: none"> <li>The notification is in the form of an attestation, and must be submitted every 2 years, during the same timeframe as the facility is required to update its facility registration</li> </ul>
<ul style="list-style-type: none"> <li>Low-risk, on-farm activities performed by small business (&lt; 500 full-time employees, company wide); or</li> <li>Low-risk, on farm activities performed by a very small business (less than \$2.5 M in animal food sales/value)</li> </ul>	Small and very small on-farm businesses conducting only low-risk activities ( <i>e.g.</i> , re-packing roughage products or cracking grains) are exempt from the Final Rules hazard analysis and preventive controls requirements.
Activities subject to the “low-acid canned food” requirements (21 C.F.R. part 113)	“Low-acid canned foods” are <i>only</i> exempt from microbiological hazard controls under the Final Rule because they are covered by part 113
Activities of a facility subject to section 419 of the FD&C Act (standards for produce safety)	These activities will fall under FDA’s forthcoming produce safety rule
Facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing	A facility that stores fruits and vegetables is not exempt
A facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.	Modified requirements apply for the storage of unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

Although “qualified” facilities may elect to be exempt from subpart C, FDA may withdraw a qualified facility’s exemption: (1) in the event of an active investigation of a foodborne illness outbreak that is directly linked to the facility; or (2) if FDA determines that it is necessary to protect the public (human and animal) health and prevent or mitigate a foodborne illness outbreak based on relevant conditions or conduct at the qualified facility. The procedure for withdrawal of a qualified facility exemption is located in subpart D of the Final Rule.

**b. Hazard Analysis**

A registered facility subject to Subpart C must conduct a hazard analysis to identify and evaluate whether there are any known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether preventive controls are required.

A facility's hazard analysis should identify known or reasonably foreseeable biological, chemical (including radiological), and physical hazards.<sup>7</sup> FDA has indicated that the known or reasonably foreseeable hazards should include: (i) naturally occurring hazards (*e.g.*, aflatoxin, *Salmonella*); (ii) unintentionally introduced hazards (*e.g.*, debris); and (iii) hazards intentionally introduced for purposes of economic gain that affect the safety of the food (*e.g.*, melamine in pet food). A hazard analysis should take into consideration the known uses of the feed ingredient. For instance, if a feed product or ingredient is likely to be used in a sheep's diet, whether there is a potential for copper toxicity should be taken into consideration. Facilities are not required to develop flow charts to identify all known or reasonably foreseeable hazards, however, in practice this may be a helpful approach.

After all known or reasonably foreseeable hazards are identified, a facility is required to identify the hazards that need to be mitigated through the implementation of preventive controls.<sup>8</sup> FDA has the authority to review and contest conclusions of a hazard analysis.

### **c. Food Safety Plan**

Subpart C of the Final Rule is anchored by the written food safety plan.<sup>9</sup> If a facility identifies a hazard requiring a preventive control, then the facility must develop a written food safety plan to address each hazard that requires a preventive control. The written food safety plan must include the following:

- Written hazard analysis (§ 507.33(a)(2));
- Written preventive controls (§ 507.34(b));
- Written supply-chain program (subpart E);
- Written recall plan (§ 507.38(a)(1));
- Written preventive control monitoring procedures (§ 507.40(a)(1));
- Written corrective action procedures (§ 507.42(a)(1)); and
- Written verification procedures (§ 507.49(b)).

FDA has the authority to review and require revisions to the written food safety plan. Furthermore, a written copy of the food safety plan must be present on-site at the facility at all times.

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<sup>7</sup> 21 C.F.R. § 507.33.

<sup>8</sup> FDA does recognize in the preamble to the Final Rule that a facility may conduct its hazard analysis and conclude there are no hazards that require a preventive control. It provides several examples of animal food products for which it believes a facility may determine there are no hazards. These include alfalfa cubes, vegetable oils and molasses.

<sup>9</sup> 21 C.F.R. § 507.31.

#### d. Preventive Controls

Facilities that are subject to subpart C and have identified hazards that need to be controlled and mitigated to protect human and animal health must implement preventive controls.<sup>10</sup> Under the Final Rule, preventive controls need to be implemented at critical control points (CCPs), if any exist. Preventive controls, other than those at CCPs, should be implemented when appropriate for animal food safety.

Preventive controls include:

- **Process Controls** – Procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. This should include: (1) the parameters associated with the control of the hazard; and (2) the maximum or minimum value, or combination of values to which any hazard must be controlled.
- **Sanitation Controls** – Procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition “adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling.”
- **Supply Chain Controls** – Facilities must comply with the supply-chain program contained in subpart E (discussed in Section V of this memo).
- **Recall Plans** – Each registered facility must have a recall plan in place for animal foods that are subject to preventive controls.
- **Preventive Controls Qualified Individual** – The Final Rule establishes a new title, the “preventive controls qualified individual (PCQI).” The PCQI is a qualified individual who has successfully completed certain training in the development and application of risk-based preventive controls or is otherwise qualified through job experience to develop and apply a food safety system<sup>11</sup>.
- **Preventive Control Management** – There are several preventive control management procedures required by the Final Rule to ensure that preventive controls

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<sup>10</sup> 21 C.F.R. § 507.34.

<sup>11</sup> It is important to note that all individuals who perform activities required under Part 507 are expected to know how to do their jobs. Based on this, § 507.4(b) was added specifying all individuals performing required activities be “qualified individuals” – “a person who has the necessary education, training, and experience to perform an activity required under Part 507.” Qualified individuals are separate from PCQI who is a specific individual with training to develop and apply a food safety system.

are effective at mitigating the potential for harm to human and animal health.<sup>12</sup> These include:

- Monitoring – monitor the preventive controls with adequate frequency to provide assurance that they are adequately performed (§ 507.40);
- Corrective actions and corrections – establish written corrective actions to be taken if preventive controls are not properly implemented (§ 507.42); and
  - “Corrective action” procedures must describe the steps taken to ensure:
    - Appropriate action taken to identify and correct problem with implementation of a preventive control;
    - Appropriate action taken to reduce reoccurrence of problem;
    - All affected animal food is evaluated for safety; and
    - All affected food is prevented from entering commerce if a facility cannot ensure the affected food is not adulterated.
  - “Correction” is defined as “an action to identify and correct a problem that occurred during the production of animal food, without other actions associated with a corrective action procedure...”<sup>13</sup>
- Verification – conduct, as appropriate to the nature of the preventive control and its role in the food safety system, documented verification and validation<sup>14</sup> activities to ensure that preventive controls are consistently implemented and effective to mitigate risks to human and animal health (§ 507.42).<sup>15</sup>

## V. SUPPLY-CHAIN COMPLIANCE

Animal food facilities are required to have a risk-based supply chain program for those raw materials and other ingredients for which they identify a hazard requiring a supply-chain-

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<sup>12</sup> 21 C.F.R. § 507.39.

<sup>13</sup> 21 C.F.R. § 507.3.

<sup>14</sup> FDA recognizes that not all preventive controls require validation such as sanitation controls, the recall plan, and the supply-chain program. It requires that the PCQI prepare a written justification on why validation is not applicable if they determine that to be the case for a preventive control.

<sup>15</sup> Based on comments received on FDA’s question on requiring a review of complaints as part of verification, FDA is *not* establishing a review of complaints as a verification activity. It does, however, encourage such a review.

applied control program.<sup>16</sup> For example, a dry dog food company may purchase corn for their product. The company determines it is appropriate to rely on their supplier for the control of the chemical hazard aflatoxin. They implement a written supply-chain program and verify that the aflatoxin has been significantly minimized or prevented by the supplier and that the level of aflatoxin in the corn does not render it adulterated under the FD&C Act. The dry dog food company recognizes their production process will address the biological hazard *Salmonella*. The dry dog food company implements preventive controls for this hazard.

As demonstrated in the example, the supply-chain program must be written and must provide assurance that the hazard requiring the supply-chain-applied control has been significantly minimized or prevented.

Animal food facilities are responsible for ensuring that raw materials and other ingredients with a supply-chain-applied control are received only from approved suppliers, or are only received on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subject to verification activities before being accepted for use. Approved suppliers are defined as facility/ies that have been approved after a consideration of factors that include: a hazard analysis of the food, the entity that will be controlling that hazard, and supplier performance. The receiving facility will not have to implement a preventive control but will have to disclose that the food is “not processed to control (identified hazard)” and also obtain annual written assurance from its customer<sup>17</sup> regarding certain actions that customer agrees to take.

The supply-chain program must include:

- Using approved suppliers;
- Determining appropriate supplier verification activities;
- Conducting supplier verification activities;
- Documenting supplier verification activities; and
- When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility’s supplier and documenting that verification.

Verification activities may include:

- Annual on-site audits;

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<sup>16</sup> The Final Rule provides an exemption for a receiving facility that is an importer and that can demonstrate compliance with the foreign supplier verification requirements under part 1, subpart L of this chapter, that maintains documentation of verification activities conducted under § 1.506(e) of this chapter (providing assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented). The requirements also do not apply to animal food supplied for evaluation or research; the food is labeled as such, not sold to the public, and is produced in quantities consistent with research or analysis.

<sup>17</sup> When the term “customer” is used in these provisions, it means a commercial customer – not a consumer.

- Sampling and testing;
- Review of the suppliers food safety records; and
- Other activities based on the risk.

In addition to the written program, records required to be maintained by the receiving facility include:

- Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements, including documentation of verification activities;
- Documentation of the approval of a supplier;
- Procedures for receiving raw materials and other ingredients;
- Documentation that demonstrates the use of the written procedures for receiving raw materials and other ingredients;
- Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;
- Documentation of onsite audits. This documentation must include:
  - Supplier name subject to the onsite audit;
  - Documentation of audit procedures;
  - Audit dates;
  - Audit conclusions;
  - Corrective actions taken in response to any findings; and
  - Demonstration completed by qualified auditor.
- Documentation of sampling and testing conducted. Documentation must include:
  - Identification of the raw material or other ingredient tested (*e.g.*, lot number) and the number of samples tested;
  - Identification of the test(s) conducted, and the analytical method(s) used;
  - Date(s) on which the test(s) were conducted and the date of the report;
  - The results of the testing;
  - Corrective actions taken in response to test results; and
  - Information on the laboratory conducting the testing.
- Documentation of the review of the supplier's food safety records, including:
  - Name of the supplier;
  - Date of the record and date of review;
  - General nature of records reviewed;
  - Conclusions of the review; and
  - Corrective actions taken in response to any findings.
- Documentation of other verification activities.<sup>18</sup>

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<sup>18</sup> A Qualified Facility might provide written assurances of compliance with applicable FDA regulations for their facility.

With regards to verification of the supplier, the rule does indicate that an inspection by FDA (or their representatives) to verify compliance with FDA requirements may be used rather than an audit if the inspection was conducted in the past year. For foreign suppliers in those countries that FDA has determined to have equivalent food safety systems,<sup>19</sup> documentation of an FDA inspection or an inspection by the competent regulatory authority in the past year could be used.

## VI. RECORDKEEPING REQUIREMENTS

Subpart F of the Final Rule details the various records that facilities must maintain related to monitoring and verification of preventive controls.<sup>20</sup> The major recordkeeping provisions include:

- **Two-Year Retention Requirement** – All records required under the Final Rule relating to preventive controls must be retained for at least two years.<sup>21</sup> Records that a facility relies upon to support its status as a qualified facility must be retained for three years.
- **Remote Record Storage** – Except for the written food safety plan, all records required under the Final Rule may be stored remotely or electronically, so long as these documents can be retrieved and provided onsite within 24 hours.<sup>22</sup>
- **Food Safety Plan** – A physical copy of a facility’s food safety plan must be maintained onsite.
- **Use of Existing Records** – Records that are kept to comply with other federal, state, or local regulations do not need to be duplicated to satisfy the Final Rule’s recordkeeping requirements.<sup>23</sup> Furthermore, the information required by the Final Rule does not need to be kept in one set of records.
- **Records Availability** – Records required by this part must be made available to an authorized representative of the Secretary of Health and Human Services for official

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<sup>19</sup> It should be noted that as of August 30, 2015, the FDA does *not* have a systems recognition program for animal food and has no signed systems recognition agreements with any foreign food safety authority for animal food.

<sup>20</sup> FDA decided *not* to establish a requirement that facilities submit a “facility profile” that would have included the facility’s food safety plan, and required biannual updates tied to the food facility registration process. This decision was based on the many comments received expressing concern with this proposed requirement.

<sup>21</sup> 21 C.F.R. § 507.208.

<sup>22</sup> 21 C.F.R. § 507.208(c).

<sup>23</sup> 21 C.F.R. § 507.212.

review and *copying upon oral or written request.*<sup>24</sup>

## VII. COMPLIANCE DEADLINES

The effective date for compliance with the Final Rule’s CGMPs and Preventive Controls is staggered and varies based on the size of the facility’s business. “Small” (less than 500 employees, company-wide) and “Very Small” (less than \$2.5M in animal food sales, 3 year avg.) businesses receive additional time to come into compliance with the Final Rule. The definitions for these special size classifications are as follows:

The compliance timelines for entities to implement CGMPs and Preventive Controls are detailed in the below table.

Business Size	CGMP Compliance Date	Preventive Controls Compliance Date
Business other than small or very small	Sept. 19, 2016	Sept. 18, 2017
Small business	Sept. 18, 2017	Sept. 17, 2018
Very small business	Sept. 17, 2018	Sept. 17, 2019 (except records to support “very small business” status due by Jan. 1, 2017)

- **Supply-Chain Program Compliance** – There is a modified timeline for facilities to comply with subpart E. The below table outlines the compliance deadlines for different circumstances.

Situation	Compliance Date
A receiving facility is a small business and its supplier will be subject to the CGMPs, but not the preventive control requirements, of the animal food preventive controls rule	6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule
A receiving facility is a small business and its supplier is subject to the animal food preventive controls rule	The later of: September 17, 2018 or 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with this rule

<sup>24</sup> FDA has indicated that they intend to copy records on a case-by-case basis as “necessary and appropriate.” In the preamble, FDA indicates that they “primarily intend to copy records such as results of product testing or environmental monitoring when we conduct an inspection for cause....”

<p>A receiving facility is not a small business or a very small business and its supplier will be subject to CGMPs, but not the preventive control requirements, of the animal food preventive controls rule</p>	<p>6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the CGMP requirements of this rule</p>
<p>A receiving facility is not a small business or a very small business and its supplier will be subject to the animal food preventive controls rule</p>	<p>The later of: September 18, 2017 or 6 months after the receiving facility’s supplier of that raw material or other ingredient is required to comply with the applicable rule</p>

**VIII. USEFUL RESOURCES**

- Final Rule – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, *available at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21921.pdf>*.
- FDA - FSMA Final Rule for Preventive Controls for Animal Food resource page, *available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm>*
- FDA FSMA Technical Assistance Network – *provides technical assistance for industry, regulators, academia, consumers and others regarding FSMA implementation. Users can submit inquiries to FDA staff – available at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>*.
- Food Safety Preventive Controls Alliance – *public/private alliance consisting of key industry, academic, and government stakeholders. Develops nationwide core curriculum, training, and outreach programs to assist in compliance with preventive controls regulations – available at: <https://www.ifsh.iit.edu/fspca>*.
- Draft Guidance for Industry – Current Good Manufacturing Practice Requirements for Food for Animals, *available at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499200.pdf>*
- Draft Guidance for Industry – Human Food By-Products For Use As Animal Food, *available at: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf>*

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I trust that this information is useful. If you have any questions, feel free to contact me at [jdillard@ofwlaw.com](mailto:jdillard@ofwlaw.com)