crowell moring

CLIENT ALERT

FDA Proposes Rule Imposing New Requirements for Manufacturing Practices, Hazard Analysis, and Preventive Controls for Animal Foods

Nov.21.2013

Continuing its mandate to implement the Food Safety Modernization Act (FSMA), the U.S. Food and Drug Administration (FDA) proposed a new rule on October 29, 2013 that would require those domestic and foreign facilities that must register with the agency to establish procedures implementing current good manufacturing practices (CGMPs) in the manufacturing, processing, packing, and holding of animal food. The proposed rule would also require certain facilities to establish and implement hazard analysis and risk-based preventive controls for animal food. These proposed requirements closely track those in the agency's previously proposed rule for human food.

The proposed CGMPs establish baseline manufacturing practices for facilities manufacturing, processing, packing, and holding animal food, including specific requirements for:

- **Personnel, including good hygiene practices and avoiding contamination from personal effects;**
- **Proper cleaning, maintenance, and elimination of pests from the grounds;**
- **Sanitary operations, including food contact surfaces and proper use and storage of toxic substances;**
- **Sanitary facilities, including the water supply, plumbing, and bathrooms;**
- **Equipment and utensils;**
- **Processes and controls, including labeling and raw materials; and**
- **Warehousing and distribution.**

The proposed rule also require covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the proposed rule would establish requirements for:

Recent Happenings in APRM November 2013

- Buckyballs® CEO Files Action Against CPSC
- Federal Appeals Court Hears Argument Regarding Sealing of 'Company Doe' Challenge to CPSC Database Publication
- FDA Proposes Rule Imposing New Requirements for Manufacturing Practices, Hazard Analysis, and Preventive Controls for Animal Foods
- CPSC Approves Publication of Proposed Voluntary Recall Rule
- Google's Book-Scanning Program is Ruled 'Fair Use'
- In The Wake of Recent Supreme Court's Decisions, FDA Proposes Change to Generic Drug Labeling Rule

- A written food safety plan;
- A written hazard analysis that identifies and evaluates known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at the facility to determine whether there are hazards that are reasonably likely to occur and an assessment of the severity of the potential consequences;
- Written preventive controls for hazards that are reasonably likely to occur, including, as appropriate:
- Monitoring the preventive controls to provide assurance that they are performed consistently;
- Written corrective action procedures to be utilized if preventive controls are not properly implemented or if there are unanticipated issues;
- Verification that the above requirements are being satisfied; and
- Maintaining records for the above requirements.

Under the proposed rule, a covered facility would have to re-assess its food safety plan at least once every three years.

The proposed rule exempts a number of entities from all or some of the new requirements and imposes modified requirements for other entities. For instance, there are modified requirements for "qualified facilities," that is businesses with average annual sales of animal food of less than $500,000 with at least half the sales to consumers, local retailers, or local restaurants, or very small businesses. The proposed rule includes three possible definitions for "very small business": a business with total annual sales of animal food of less than $500,000, $1 million, or $2.5 million. FDA has requested comments as to which definition it should adopt.

Qualified facilities will have to demonstrate that the facility is qualified and:

- Demonstrate that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or
- Demonstrate that the facility is in compliance with state, local, county, or other applicable non-Federal food safety law.

The proposed rule also imposes modified requirements for facilities solely engaged in the storage of packaged animal food that is not exposed to the environment. Such facilities would still need to conduct certain activities for any such refrigerated packaged animal food that requires time or temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of animal or human health significance, including:

- Establishing and implementing temperature controls;

- **Monitoring the temperature controls;**
- **Taking appropriate corrective actions when there is a problem with temperature controls;**
- **Verifying that temperature controls are consistently implemented; and**
- **Establishing and maintaining records for the above.**

The final rule would be effective 60 days after it is published, however, FDA has tentatively proposed that enforcement would not begin until one year after publication of the final rule. Small business and very small businesses would have two years and three years, respectively to comply. Any comments on the proposed rule are due February 26, 2014.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com