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FDA issues new administrative detention/suspension authority

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As required by the Food Safety Modernization Act (FSMA), the Food and Drug Administration is issuing new regulatory criteria for the detention of human or animal feed.

“The FDA can order administrative detention and suspension of facility registration if there is reason to believe that an article of food is adulterated or misbranded,” said Jason Young, FAPC quality management specialist. “Previously, the FDA did not have the authority to suspend a facilities’ registration.”

When the registration of a food company is suspended, the food producing facility cannot ship or sell product.

Registration of all food facilities is one of the requirements by the 2002 Bioterrorism Act. Operators in charge of domestic or foreign facilities that manufacture, pack, or hold human or animal food are required to register the facility with the FDA.

On July 3, 2011, registered facilities became subject to the suspension of registration provisions as defined in section 415(b) of the Federal Food Drug and Cosmetic Act.

If the FDA determines food manufactured, processed, packed, received or held by a facility has reasonable probability of causing serious adverse health consequences or death to humans or animals, the FDA may

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*Jason Young
FAPC Quality Management Specialist*

by order suspend the registration of the facility shutting down the food establishment.

“The processor will be given the opportunity to remove the suspension,” Young said. “Within two business days or an agreed date and time, the processor can meet with the FDA and during an informal meeting layout their case why they should be reinstated.”

The FDA may reinstate the company’s registration once it has determined the processor can produce safe food. In most cases, this will require the processor to layout a comprehensive corrective action plan, which will include identifying the cause of the incident and preventive measures. The future product does not have the reasonable probability of causing serious adverse health consequences or death.

This new modified FDA Administrative Detention Authority changed the criteria or ordering administrative detention of human or animal food. The current criteria in section 304(h) (1)(A) of the FD&C Act provide FDA the authority to order the detention of an article of food if there is “cred-

ible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.”

Section 207 of FSMA changes the criteria to allow the agency to order detention if there is “reason to believe that an article of food is adulterated or misbranded.”

The new criteria provide FDA enhanced authority to detain articles of food that may be adulterated or misbranded for 20 calendar days with a possible 10-calendar day extension, if needed to initiate legal action under section 304 or 302 of the FD&C Act (21 U.S.C. 332). This authority will further help the agency prevent potentially harmful food from reaching consumers and thereby improve the safety of the food supply in the U.S.

The primary benefits of administrative detention are the value of the illnesses or deaths prevented because the agency administratively detained food suspected of being adulterate.

For the latest updates to the FSMA, visit the FDA website at www.fda.gov/Food/FoodSafety/FSMA/default.