



Center for Food Safety and Applied Nutrition Constituent Update

FDA Issues Guidance to Allow “Co-Manufacturers” Additional Time to Implement Certain Supply-Chain Program Requirements

November 3, 2017

Today, the U.S. Food and Drug Administration (FDA) announced the availability of a guidance designed to give certain co-manufacturers more time to meet supplier approval and verification requirements under three FDA food safety regulations.

Three of the rules created to implement the FDA Food Safety Modernization Act (FSMA) – Preventive Controls for Human Foods, Preventive Controls for Animal Food, and the Foreign Supplier Verification Programs – have requirements for a supply-chain program for certain raw materials and other ingredients. This program is designed to address hazards requiring a supply-chain-applied control.

This guidance is intended for participants in “co-manufacturing” agreements in which a brand owner arranges for a second party to manufacture or process food on its behalf. The rules require co-manufacturers to whom the supply-chain program applies to approve their suppliers of certain raw materials/ingredients and conduct supplier verification activities. While the co-manufacturer is required to approve its suppliers, there is some flexibility in the rules that allows the co-manufacturer to rely on a brand owner’s supplier verification activities.

To meet the requirements of the supply-chain program, the co-manufacturer may need detailed information from the brand owner. Based on input from the food industry, FDA has determined that the industry needs more time to establish new contracts that will allow brand owners and co-manufacturers to share certain information, such as audits of suppliers.

The guidance states that FDA does not intend to take enforcement action for two years against a co-manufacturer that is not in compliance with certain supply-chain program requirements related to supplier approval and supplier verification. This enforcement discretion is conditional on the supplier approval and verification activities being divided between the brand owner and the co-manufacturer.

This guidance, entitled “Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry,” is immediately effective. You may submit electronic or written comments regarding this guidance at any time, as well as find more information, at <https://www.regulations.gov>.