October 15, 2019

Submitted electronically via regulations.gov

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD  20852

Re:  Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food; Docket No. FDA-2017-D-5996

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) is writing in support of the Food and Beverage Issues Alliance’s (FBIA’s) request that FDA extend the enforcement discretion policy announced in the Guidance entitled “Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food” beyond November 6, 2019.

As the voice of the U.S. frozen food industry, AFFI is the national trade association that represents the interests of all segments of the frozen food industry. AFFI members manufacture and distribute frozen foods throughout the United States and globally. AFFI represents a broad group of companies throughout the food distribution chain, including food producers, distributors, and retailers, many of whom engage in co-manufacturing relationships.

FBIA’s letter articulates the challenges brand owners and co-manufacturers continue to face in complying with the Preventive Controls for Human Food supply chain requirements. While we appreciate FDA’s 2017 decision to exercise enforcement discretion for two years, our members have yet to overcome the many contractual and logistical barriers to compliance with the supplier verification requirements as they relate to brand owners and co-manufacturers. An extension of the current November 6, 2019, compliance date will allow for further consultation between FDA and industry to resolve these compliance challenges.

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We appreciate FDA’s consideration of this request. We would be pleased to address any questions and to collaborate with FDA on a long-term solution to the compliance challenges facing brand owners and co-manufacturers.

Respectfully submitted,

Donna M. Garren, Ph.D.
Executive Vice President, Science and Policy