October 4, 2019

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

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

Dear Sir or Madam:

The below signed trade organizations are writing concerning the guidance document entitled "*Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry*" (Guidance), issued in November 2017. As explained below, the below signed trade organizations respectfully requests that FDA extend the enforcement discretion policy set forth in this Guidance beyond November 6, 2019, when it is due to lapse, because of the compliance challenges faced by much of the industry.

Background

The Guidance addresses application of the Preventive Controls for Human Food supply-chain program requirements (*e.g.*, 21 CFR Part 117, Subpart G) in co-manufacturing situations. FDA explains in the Guidance that it plans to exercise enforcement discretion for two years, until November 6, 2019, with respect to certain supplier verification requirements in situations where a brand owner performs supplier verification activities on behalf of its contract manufacturer (co-manufacturer). This enforcement discretion is conditional on the supplier approval and verification activities being clearly divided between the brand owner and the co-manufacturer. FDA explains in the Guidance that it is taking this action because industry expressed concerns that compliance with the supplier verification regulations may not be possible for co-manufacturers under existing contractual agreements.

Since the Guidance was issued many of the below signed trade organizations and their members have met with FDA about potential solutions for this complex issue and would like to continue its dialog with FDA to identify a permanent solution.

Compliance Challenges

Members of our associations have identified the following compliance challenges for situations where brand owners perform supply-chain program activities on behalf of their co-manufacturers:

- Efficiency: It is duplicative for a co-manufacturer to review and assess the supply-chain program documentation that already has been vetted by the brand owner. Because the

food is being produced on the brand owner's behalf, there are strong incentives for them to be certain that they have adequately assessed suppliers.

- Purchase Agreements: Brand owners sometimes purchase the ingredients that they require their co-manufacturers to use (*e.g.*, due to pricing considerations for volume discounts). Even if the co-manufacturer is required by the brand owner to vet these suppliers directly, the co-manufacturer may not be able to do so because they do not have a direct relationship with the supplier. Suppliers typically will not provide confidential information to third-parties with whom they have no direct relationship.

- Non-Disclosure Agreement (NDA): Brand owners typically have NDAs in place with suppliers that limit the brand owner's ability to provide documentation from the supplier to a third-party, such as a co-manufacturer. In many instances, the co-manufacturer is not able to review and assess the applicable documentation because the brand owner is not able to provide it to them.

- Contractual Limitations: Although the Guidance anticipates that companies would revise their contracts during the enforcement discretion period to enable sharing of supplier information, this has not been feasible for most companies. As companies considered revising the contracts, many realized that re-opening the contracts to other negotiations, including preparing contract addenda for each supplier. Similarly, some contracts between brand owners and co-manufacturers would need revisions to re-allocate the supply-chain program responsibility.

- Resources: Some companies have indicated that they do not have enough personnel to manage the flow of supply-chain program information from the brand owner to their multiple co-manufacturers. They would either need to incur the expense of hiring additional personnel, or reassign their resources away from other supply-chain program activities (*e.g.*, performing on-site supplier audits).

Request for Extension

We commend FDA's 2017 decision to provide industry with an additional two years to implement the Preventive Controls supply-chain program requirements in certain situations involving contract manufacturing. However, even with this additional time, there remain numerous compliance hurdles that have not been resolved. An extension of the compliance date will allow time for industry and FDA to develop a long-term resolution for this issue.

We appreciate your consideration of this request. Please do not hesitate to contact any of the below signed associations with any questions.

Sincerely,

American Bakers Association
American Frozen Food Institute
American Spice Trade Association
The Association for Dressings & Sauces
Food Marketing Institute
Grocery Manufacturers Association
Independent Bakers Association
Institute of Shortening and Edible Oils
International Food Additives Council
Juice Products Association
National Grocers Association
United Fresh Produce Association
Vinegar Institute