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MEMORANDUM

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Re: FDA Announces Pilot Program for Two-Tier Preventive Controls for Human Food Inspections under FSMA

The U.S. Food and Drug Administration (FDA) recently announced that it will engage in a pilot program to evaluate the benefits of two-tier inspections for some aspects of the Preventive Controls for Human Food (PCHF) rule under the FDA Food Safety Modernization Act (FSMA). Through a Notice to Industry, FDA is inviting food companies with multiple facilities that implement centrally developed supply-chain programs and recall plans to apply to participate in two-tier inspections. 1/ FDA plans to limit initial participation in the program to five businesses. FDA will consider the results of the two-tier inspections pilot to determine the feasibility of employing the two-tier approach to inspections on a broader scale. This memorandum summarizes the program and FDA's criteria for participation. Interested companies must notify FDA of their desire to participate no later than October 31, 2018.

Two-Tier Inspections

The two-tier inspection approach is a potential method for improving the efficiency of FDA's inspections of businesses that operate multiple food processing facilities and that develop at the corporate level the supply-chain programs and recall plans used by multiple facilities. The approach will involve two assessments, or tiers:

- **Tier 1 Inspection:** The approach begins with a Tier 1 inspection, a pre-announced, focused Preventive Controls inspection, which preferably will take place at one of the business's facilities in close proximity to corporate headquarters. During this inspection, FDA will assess the adequacy of the business's supply-chain program and recall plan to determine whether they comply with the applicable requirements in 21 C.F.R. Part 117. FDA aims to perform Tier 1 inspections at facilities in close proximity to the company's corporate headquarters to facilitate engagement between FDA and key company employees who are knowledgeable about the company's supplier verification and recall programs and the design of those programs.

1/ Two-tier Inspections – Notice to Industry (Sept. 24, 2018), available at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm620932.htm.

- **Tier 2 Inspection:** The Tier 1 inspection will inform the Tier 2 inspection, during which FDA will assess the facility's implementation of all applicable requirements in Part 117 except for the adequacy of the written the supply-chain program and recalls plans that were reviewed during Tier 1. For supply chain programs, the inspection will likely focus on the facility's written procedures for ensuring that raw materials are received only from approved suppliers. Unlike Tier 1 inspections, Tier 2 inspections will not be announced.

In other words, to improve efficiency, FDA will only assess the adequacy of supply-chain programs and recall plans that a company has put in place in multiple facilities one time, rather than repeating this assessment multiple times when it visits each individual facility.

FDA will consider the results of these initial tiered inspections to determine whether it would be feasible to implement the approach on a broader scale. If FDA determines the approach is worthwhile, it will also use its experience with the first five businesses to develop and refine its process for the two-tier inspection approach. FDA also anticipates that the tiered inspections will provide data on inspection efficiency when the agency is able to assess centrally developed programs (i.e., programs developed at the corporate level that are common to multiple food processing facilities) rather than at multiple facilities.

FDA expects that potential benefits of the two-tier inspection approach will include decreased inspection time in facilities; improved public health protection resulting from FDA's addressing food safety issues across multiple facilities; and greater opportunities for education, outreach, and communication between FDA food safety staff and industry. For businesses, additional potential benefits from tiered inspections include the ability to engage key corporate personnel to explain programs efficiently; consistent inspection determinations; and the opportunity to prepare for the pre-announced Tier 1 inspection.

Criteria and Instructions for Participation

To be eligible to participate in the two-tier inspections, businesses should have:

1. Two or more domestic registered food facilities that are subject to the PCHF rule; and
2. A supply-chain program and recall plan that were centrally developed.

FDA is limiting participation in the program to five businesses, and therefore not all businesses that apply to participate in the program will necessarily be selected. FDA will make its selections based on the total number of the business's facilities implementing the centrally developed programs and the categories or types of products at each facility requiring a supply-chain program and recall plan. FDA also expressed a preference for companies that have a facility in close proximity to the corporate headquarters.

Businesses that satisfy the criteria and wish to participate should send an email expressing their interest to FDA at: TwoTierInspections@fda.hhs.gov. The deadline for contacting FDA to express interest is October 31, 2018.

Emails to FDA should include the names, addresses, and contact persons for each business interested in participating; the facility that would participate in the Tier 1 inspection; the facilities available for Tier 2 inspections; the number of facilities implementing the centrally developed programs; and the categories or types of products at each facility. FDA will notify applicants whether they have or have not been selected using the contact information the applicant provides.

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Please contact us if you have any questions or would like to discuss the potential of participating in the two-tier inspection pilot program.