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MEMORANDUM

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Date: July 22, 2019

Re: **FDA Finalizes Guidance on How to Determine Whether a Company Meets the "Small Business" Definition under the FSMA Preventive Controls Regulations**

The U.S. Food and Drug Administration (FDA) recently finalized its "Guidance for Industry: Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food)." 1/ The Guidance is intended to help facilities determine whether they qualify as a "small business" for the purposes of Preventive Controls for Human Food (PCHF) and Preventive Controls for Animal Food (PCAF) regulations. Qualifying as a small business is significant because it may result in 1) exemptions from certain requirements for "farm mixed-type facilities" and 2) later compliance dates (which have already passed, with a few minor exceptions).

Notably, the Guidance explains that different entities within the same corporate structure may have different statuses under the rules (i.e., one entity could qualify as a small business while another does not). This memorandum provides a high-level summary of the Guidance, and we encourage any company claiming status as a small business to read the Guidance closely to confirm it is performing the analysis consistent with FDA's expectations.

"Small Business" Analysis

Both the PCHF and PCAF rules define a "small business" as a business that employs less than 500 full-time equivalent employees (FTEs), including among subsidiaries or affiliates. The 500 FTE limit includes all employees of the business and is not limited to the employees at a particular facility. FDA uses the following method to calculate the number of FTEs in a business:

1. Start with a food facility required to register.
2. Determine the legal entity that the food facility is a part of.
3. Calculate the total number of FTEs in this legal entity.
4. Determine whether the legal entity has any subsidiaries and calculate the FTEs of all the subsidiaries.

1/ Guidance for Industry: Determining the Number of Employees for Purposes of the "Small Business" Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food) (June 2019), *available at* https://www.fda.gov/media/111951/download.

5. Determine whether the legal entity has any affiliates and calculate the FTEs of all the affiliates.
6. Add the number of FTEs calculated for the legal entity, any subsidiaries, and any affiliates to get the total number of FTEs in a business.

The Guidance focuses primarily on calculating the total number of FTEs in a legal entity (step 3) and determining whether the legal entity has any subsidiaries or affiliates (steps 4 and 5).

Calculating the Number of Full-Time Equivalent Employees

For the small business analysis, a business must identify what legal entity encompasses the registered facility at issue. The business then must calculate the number of FTEs for that legal entity and all its subsidiaries and affiliates. The guidance proposes the following method for calculating FTEs:

1. Determine the total number of employees' wage or salary hours.
    a. Count all employees, including those who engage in non-food activities like management, sales, and marketing.
    b. Include hours worked by part-time and seasonal workers.
2. Divide the total number of hours worked by 2,080—the number of work hours per year.
3. Round the quotient down to nearest whole number.
4. If the number of FTEs is less than 500, then the business qualifies as a small business.

Defining Affiliates and Subsidiaries

The total number of FTEs must include the FTEs of the business's subsidiaries and affiliates. The business size calculation should be made from the perspective of the registered facility. For this reason, business size calculations may vary among different facilities in the same business structure depending on the facility's position within that business structure. Therefore, it is important to properly identify which entities constitute subsidiaries and affiliates.

Under the regulations, a "subsidiary" is a *company* that is owned or controlled by another company, which is the parent company. This means that only companies (i.e., not facilities) can have subsidiaries. An "affiliate" is a *facility* required to register with FDA that controls, is subject to the control of, or under common control with another facility. Therefore, only facilities that are required to register with FDA can be affiliates.

To illustrate this variance, the guidance explains how a facility that is part of a subsidiary may have a different FTE calculation than a facility that is part of the parent company. Both facilities would count the subsidiary's employees in their total, but facilities within a subsidiary would not count the parent company's employees, unless those employees work for the facility within the subsidiary or its affiliate facilities.

The Guidance also addresses how to identify subsidiaries and affiliates when a facility's parent company is not a facility, for franchisee relationships, and farm mixed-type facilities.

Implications of the Small Business Designation

There are two implications of qualifying as a small business under the PCHF or PCAF rule. First, a small business that operates a farm mixed-type facility is exempt from the human food preventive controls requirements under Part 117 if it engages in certain low-risk activity/food combinations listed

in 21 C.F.R. § 117.5(g) and (h). This same principle also applies to animal food preventive control requirements under part 507, so long as the farm mixed-type facility only conducts the low-risk activity/food combinations outlined in 21 C.F.R. § 507.5(e) and (f).

Second, a small business is subject to later compliance dates under parts 117 and 507, which have already passed (with a few minor exceptions). 2/ The small business compliance date for the PCHF rule was September 18, 2017. The small business compliance date for the PCAF rule was September 18, 2017 for compliance with Subpart B's cGMP requirements, and the compliance date for Subpart C's preventive controls requirements was September 17, 2018.

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We will continue to monitor FDA's implementation of FSMA regulations. Please contact us with any questions regarding this or other matters in the meantime.

2/ For example, the compliance date for the preventive controls requirements under the PCAF rule is January 27, 2020 for facilities solely engaged in packing and/or holding activities on produce raw agricultural commodities and/or nut hulls and shells for animal food.