Big Breaks for Very Small Food Companies

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New guidance from the Food and Drug Administration could mean a hefty cost compliance savings for "very small" companies.

The FDA released the new guidance in September to help food producers determine their status as "qualified facilities" under regulations regarding current Good Manufacturing Practice, hazard analysis, and risk-based preventative controls for human and animal food. This non-binding guidance clarifies which companies may avail themselves of the modifications, potentially providing huge cost-of-compliance savings for "very small" companies.

The full text of the guidance document can be found here.

Qualified facilities remain subject to current Good Manufacturing Practices requirements for human food and animal food as set forth by certain federal laws. However, the modified requirements for qualified facilities are intended to relieve small facilities of the more onerous requirements of the hazard analysis and risk based preventative controls requirements, as well as supply chain program requirements. Instead, the modified requirements allow facilities to submit statements to the FDA confirming that the qualified facility has identified potential hazards, has preventative controls in place and is monitoring such controls. The facility could also confirm the facility meets all requirements of state, local, county or tribal food law, including applicable food safety permits, licenses and certificates.

The facility must also submit a statement of its qualified status. Companies should note that the FDA provides separate forms for qualified facilities for human food and qualified facilities for animal food. For facilities that began producing either human or animal food before Sept. 17, the deadline to submit verification is Dec. 17. For those that began producing between Sept. 17 and Sept. 17, 2019, the deadline is Dec. 17, 2019. Beginning in the year 2020, these verifications will need to be updated and resubmitted every two years during the biennial registration period that is open from Oct. 1 to Dec. 31.

So, what facilities qualify? FDA defines a qualified facility by one of two methods. Either can be used to be deemed a qualified facility:

- A business averaging less than $1 million per year for the sale of food; or
- A business whose average monetary value of food sold to qualified end-users exceeds the average monetary value of food sold to other purchasers and the average value of food sold was less than $500,000 per year.

Averages are calculated from the preceding three-year period, and are adjusted for inflation from 2011 values. Interestingly, the FDA's guidance clarifies that a subsidiary can be a qualified facility, even if the parent company is not. The FDA relies on each facility to determine its status as a qualified facility, subject to FDA verification.

If you have any questions regarding the status of your company as a qualified facility, or would like assistance

registering your facility as "qualified," please contact me.

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