Health Law Daily Wrap Up, FOOD STANDARDS—FDA GUIDANCE NOTICES: Farm definition impacts food facility registration, (Nov. 19, 2014)

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The FDA has issued a guidance notice titled, “Questions and Answers Regarding Food Facility Registration (Sixth Edition).” The revised edition includes an additional question and answer regarding food facility registration for farms defined in continued rulemaking under the FDA Food Safety Modernization Act (FSMA) (Notice, 79 FR 68810, November 19, 2014).

Background. Section 415 of the federal Food, Drug, and Cosmetic Act (FDC Act) (21 U.S.C. 350d) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA. The FSMA (P.L. 111-353) was enacted on January 4, 2011, and amended the food facility registration requirements in section 415 of the FDC Act.

The FSMA continued rulemaking proposes to make certain changes to the definition of the term “farm” (21 C.F.R. 1.227). The sixth edition, which is a level I guidance, includes one additional question and answer relating to these changes noted in the September 2014 supplemental notice of proposed rulemaking for preventive controls for human food (79 FR 58524).

“Farm.” The current definition of a “farm” includes facilities that are not only devoted to the growing and harvesting of crops or the raising of animals, but includes those that also pack or hold food grown, raised, or consumed on that farm or another farm under the same ownership.

In contrast, the additional question and answer explains the FDA’s policy regarding food facility registration for farms that also pack or hold raw agricultural commodities grown on a farm under different ownership. If the proposed definitional changes are finalized, these farms would no longer be required to register with the FDA. Under the policy, the FDA does not intend to prioritize enforcing the registration requirement for these types of establishments.

The guidance notice covers other food facility registration requirements, as well as the consequences for failing to register, renew, or cancel the registration. The guidance notice is effective immediately, because the FDA has determined that prior public participation is not appropriate. The revision is available on the FDA’s website.

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