4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket No. FDA-2016-D-2373]

Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry." The draft guidance, when finalized, will help food establishments determine whether the activities that they perform are within the "farm" definition established in our regulation for Registration of Food Facilities. Determining whether the activities a food establishment performs are within the "farm" definition plays a key role in determining whether its business is exempt from our regulations for Registration of Food Facilities, and from certain requirements in our regulations for "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals."

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we begin work on the final

version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-2373 for "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled "Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities." We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is

not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

Section 103(c) of the FDA Food Safety Modernization Act (FSMA) directed us to conduct rulemaking to clarify the on-farm activities that would, in part, determine when an establishment is required to register with us as a "facility," or is not required to register with us because the establishment is a "farm." To do so, we conducted rulemaking to revise and add farm-related definitions to our existing regulation for Registration of Food Facilities in the same rulemaking documents that we issued to establish our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" in part 117 (21 CFR part 117). (See the final rule at 80 FR 55908, September 17, 2015). For the purposes of the draft guidance, we call that rulemaking "the farm definition rulemaking." The farm definition rulemaking revised the "farm" definition to provide for two types of farms: (1) Primary production farms and (2) secondary activities farms. The farm definition rulemaking also revised three definitions associated with the "farm" definition (i.e., the definitions of "packing," "holding," and "manufacturing/processing") and added more examples of activities in each of these definitions. The farm definition rulemaking also established a new definition associated with the "farm" definition (i.e., the definition of "harvesting") and included examples of harvesting activities in the definition. During the farm definition rulemaking, several comments asked us to classify specific on-farm activities as harvesting, packing, holding, or manufacturing/processing so that an operation that conducts these activities on a farm can determine whether conducting that specific activity is within, or outside, the "farm" definition. Some comments asked us to make a table of activities prominently available on our Internet site for easy access whenever the public seeks out information regarding regulations to which these

activities apply. (See 80 FR 55908 at 55920.) To address these comments, we announced our intent to issue a draft guidance with our current thinking on the classification of activities as "harvesting," "packing," "holding," or "manufacturing/processing" (80 FR 55908 at 55921). The draft guidance that we are making available implements that stated intent.

The draft guidance provides examples of activities classified as "harvesting," "packing," "holding," or "manufacturing/processing," as well as activities classified in more than one way. We note that the list of examples of activities classified as "holding" in the draft guidance does not include "repacking and blast freezing… when product is not exposed to the environment," despite our statement in the farm definition rulemaking that such activities would be considered practical necessities for distribution and therefore "holding." See 80 FR 55908 at 55934 (Comment/Response 44). We made similar statements in a related rulemaking to establish our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" in part 507 (21 CFR part 507) (80 FR 56170, September 17, 2015). See 80 FR 56170 at 56192 (Comment/Response 39). Our prior statements were incorrect and we hereby withdraw them. Neither "repacking" nor "blast freezing" should be considered a "holding" activity. We have thought more about what should be considered a "practical necessity" and are explaining our thinking more in the draft guidance.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 1, subpart H have been approved under OMB control number 0910-0502. The collections of information in part 117 have been

approved under OMB control number 0910-0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910-0789. The collections of information in 21 CFR part 112 have been approved under OMB control number 0910-0816. The collections of information in 21 CFR part 121 have been approved under OMB control number 0910-0812.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: August 19, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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