

TABLE 1—THE FOUR FOUNDATIONAL FSMA RULES RELEVANT TO THE DRAFT GUIDANCE—Continued

Title and abbreviations for the purpose of this document	Regulatory codification	“Customer provisions”	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (part 507).	21 CFR part 507	21 CFR 507.36(a)(2), (3), and (4).	80 FR 56170, September 17, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce safety regulation).	21 CFR part 112	21 CFR 112.2(b)	80 FR 74354, November 27, 2015.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (FSVP regulation).	21 CFR part 1, subpart L ..	21 CFR 1.507(a)(2)(i), (a)(3)(i), and (a)(4)(i).	80 FR 74226, November 27, 2015.

The “customer provisions” of part 117 and part 507 each include a requirement for a “disclosure statement” in which a manufacturer/processor must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]” in certain circumstances. Likewise, the “customer provisions” of the FSVP regulation include a requirement for a “disclosure statement” in which an importer must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to control [identified hazard]” in certain circumstances. The “customer provisions” of the produce safety regulation relate to an exemption from that regulation that includes a requirement for a “disclosure statement” in which a farm must disclose, in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.”

The draft guidance responds to industry questions regarding these requirements for a disclosure statement. On March 23, 2016, FDA met with a food trade association at their request to listen to concerns regarding the customer provisions of part 117 (Ref. 1), including concerns regarding the disclosure statement in part 117. At the meeting, the trade association expressed concern about providing a disclosure statement when multiple hazards may be present, including chemical hazards (such as mycotoxins) and physical hazards (such as stones in raw agricultural commodities), as well as for multiple biological hazards (such as microbial pathogens). The trade association also asked us to allow a variety of types of documents that accompany the food to have the disclosure statement (e.g., contractual agreements, Web sites referenced on labels and in contracts, letters of guarantee, shipment-specific certificates

of analysis, shipping documents, specifications, and terms and conditions).

The trade association focused its discussion on the requirements of part 117, but noted that it had parallel concerns for the analogous provisions of part 507 and the FSVP regulation (Ref. 1). Although the trade association did not express concern with the disclosure statement in the produce safety regulation, we believe it will be helpful to businesses subject to the produce safety regulation, to include our current thinking on the disclosure statement in all four rules that have requirements for a disclosure statement, not just the three rules mentioned by the trade association.

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 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 1, subpart L have been approved under OMB control number 0910–0752.

III. Electronic Access

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

IV. References

The following references are on display in the Division of Dockets Management, 5630 Fishers Lane, Rm.

1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

1. Grocery Manufacturers Association, “21 CFR 117.136. Industry Impacts from Disclosure and Written Assurance Requirements,” 2016.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 58

[Docket No. FDA–2010–N–0548]

Good Laboratory Practice for Nonclinical Laboratory Studies; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the proposed rule that appeared in the **Federal Register** of August 24, 2016. In the proposed rule, FDA requested comments on its proposal to amend the regulations for good laboratory practice for nonclinical studies. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the proposed rule published August 24, 2016 (81 FR 58342). Submit either electronic or written comments by January 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-2010-N-0548 for "Good Laboratory Practice for Nonclinical Laboratory Studies." 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.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., MPN4-142, Rockville, MD 20855, 240-402-5637; or Kristin Webster Maloney, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4373, Silver Spring, MD 20993, 240-402-4993.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 2016, FDA published a proposed rule with a 90-day comment period to request comments on its proposal to amend the regulations for good laboratory practice for nonclinical studies. Comments on the proposed amendments will inform FDA's rulemaking to establish regulations for good laboratory practice for nonclinical laboratory studies.

The Agency has received requests for a 90-day extension of the comment period for the proposed rule. Each request conveyed concern that the

current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 60 days, until January 21, 2017. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: October 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 250

[Docket ID: DOD-2015-OS-0126]

RIN 0790-A173

Withholding of Unclassified Technical Data and Technology From Public Disclosure

AGENCY: Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics, DoD.

ACTION: Proposed rule.

SUMMARY: This rulemaking establishes policy, assigns responsibilities, and prescribes procedures for the dissemination and withholding of certain unclassified technical data and technology subject to the International Traffic in Arms Regulations (ITAR) and Export Administration Regulations (EAR). It applies to DoD components, their contractors and grantees and is meant to control the transfer of technical data and technology contributing to the military potential of any country or countries, groups, or individuals that could prove detrimental to U.S. national security or critical interests.

DATES: Comments must be received by December 30, 2016.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- **Federal Rulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350-1700.