



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6133]

Application of the “Solely Engaged” Exemptions in Parts 117 and 507; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “Application of the “Solely Engaged” Exemptions in Parts 117 and 507; Draft Guidance for Industry.” The draft guidance, when finalized, will help establishments and facilities subject to certain FDA regulations determine whether they are “solely engaged” in certain activities. Establishments and facilities “solely engaged” in certain activities are exempt from some or all requirements of the regulations.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-6133 for "Application of the "Solely Engaged" Exemptions in Parts 117 and 507: Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Food Safety (HFS-300), Center for Food Safety and Applied Nutrition, 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: *For questions relating to the guidance as it applies to human food:* Jenny Scott, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166. *For questions relating to the guidance as it applies to animal food:* Jeanette Murphy, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a draft guidance for industry entitled “Application of the “Solely Engaged” Exemptions in Parts 117 and 507.” 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. This guidance is not subject to Executive Order 12866.

This guidance concerns two regulations that we have established in Title 21 of the Code of Federal Regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). These two regulations are part 117 (published in the *Federal Register* on September 17, 2015, 80 FR 55908 and part 507 (published in the *Federal Register* on September 17, 2015, 80 FR 56170). This guidance is intended to help establishments and facilities subject to part 117 or part 507 determine whether they are “solely engaged” in certain activities. Establishments and facilities “solely engaged” in certain activities are exempt from some or all requirements in parts 117 or 507.

Parts 117 and 507 contain exemptions specific to establishments and facilities “solely engaged” in certain activities. The relevant exemptions can be categorized as follows: (1) exemption from human food current good manufacturing practice (CGMP) requirements, (2) exemption from human food preventive controls requirements, (3) exemption from animal food CGMP requirements, and (4) exemption from animal food preventive controls requirements.

This draft guidance, when finalized, will clarify that if all of the activities performed by an establishment are exempt under one or more CGMP exemptions, then the establishment is not subject to the part 117 and/or part 507 CGMPs, as applicable. If all the activities performed by a facility are exempt under one or more preventive controls exemptions, then the facility is not subject to the part 117 and/or part 507 preventive controls requirements, as applicable. If all the activities performed by a facility are exempt under one or more CGMP exemptions and one or more preventive controls exemptions, then the facility is not subject to the CGMP or preventive controls requirements in part 117 and/or part 507, as applicable.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either [https://www.fda.gov/FoodGuidances\\_or](https://www.fda.gov/FoodGuidances_or) <https://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153033.htm> (whichever is applicable) or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 16, 2017.

Anna K. Abram,

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

[FR Doc. 2017-22731 Filed: 10/19/2017 8:45 am; Publication Date: 10/20/2017]