DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 117 and 507

[Docket No. FDA–2018–D–0671]

Determining the Number of Employees for Purposes of the ''Small Business'' Definition (Current Good Manufacturing Practices and Preventive Controls Regulations for Human and Animal Food): Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry describing the Agency's current thinking on how to determine the number of employees for purposes of the ''small business'' definition in the current good manufacturing practice (CGMP), hazard analysis, and risk-based preventive controls for human and animal food rules. The guidance will help industry subject to these rules determine the number of employees for purposes of the ''small business'' definition.

DATES: The announcement of the guidance is published in the **Federal Register** on June 21, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–0671 for ''Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food): 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 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 guidance to the 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 guidance.

FOR FURTHER INFORMATION CONTACT:

For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food: 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.

For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Jeanette Murphy, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6246.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507 (CGMP and Preventive Controls Regulations for Human and Animal Food): Guidance for Industry.'' We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of 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 alternative 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 (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353). These two regulations are part 117 (21 CFR part 117) (September 17, 2015, 80 FR 55907) and part 507 (21 CFR part 507) (September 17, 2015, 80 FR 51670). Under parts 117 and 507, whether a business is a ''small business'' has two main implications. First, certain small businesses are exempt from the human food preventive controls requirements and the animal food preventive controls requirements if they are engaged only in specified low-risk activity/food combinations. Second, small businesses have later compliance dates for parts 117 and 507 than larger businesses. This guidance provides additional information to assist businesses in determining their status as a ''small business.''

In the **Federal Register** of March 20, 2018 (83 FR 12143), we made available a draft guidance for industry entitled ''Determining the Number of Employees for Purposes of the 'Small Business' Definition in Parts 117 and 507: Guidance for Industry'' and gave interested parties an opportunity to submit comments by May 21, 2018, for us to consider before beginning work on the final version of the guidance. We received no substantive comments on the draft guidance and are issuing the guidance with editorial changes to improve clarity and revision of one example to improve usefulness. The guidance announced in this notice finalizes the draft guidance dated March 2018.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: June 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13223 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 501

Reporting, Procedures and Penalties Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is issuing this interim final rule to amend the Reporting, Procedures and Penalties Regulations (the Regulations) to provide updated instructions and incorporate new requirements for parties filing reports on blocked property, unblocked property, or rejected transactions. In addition, OFAC is revising the licensing procedures section of the Regulations to include information regarding OFAC's electronic license application procedures and to provide additional instructions regarding applications for the release of blocked funds. OFAC also is clarifying the rules governing the availability of information under the Freedom of Information Act (FOIA) for information that is submitted to OFAC pursuant to the Regulations. Finally, OFAC is making numerous technical and conforming edits throughout the Regulations.

DATES: This interim final rule is effective June 21, 2019. Written comments may be submitted on or before July 22, 2019.

ADDRESSES: You may submit comments by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions on the website for submitting comments. Refer to Docket Number OFAC–2019–0003.

Fax: Attn: Request for Comments (Amendments to OFAC's Reporting, Procedures and Penalties Regulations) 202–622–1759.

Mail: Attn: Request for Comments (Amendments to OFAC's Reporting, Procedures and Penalties Regulations), Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Freedman's Bank Building, Washington, DC 20220. Refer to Docket Number OFAC–2019–0003.

Instructions: All submissions received must include the agency name and the **Federal Register** Doc. number that appears at the end of this document. All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Comments generally will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: *OFAC:* Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Background

The Regulations set forth standard reporting and recordkeeping requirements and license application and other procedures relevant to the economic sanctions programs administered by OFAC. OFAC is updating six sections of the Regulations.

Reports on Blocked and Unblocked Property

OFAC is revising § 501.603 of the Regulations, which covers reports on blocked property, to provide greater detail regarding the information required to be provided to OFAC in connection with blocking reports and to expand this section to cover reports on the release of property from blocked status (*i.e.,* unblocked property), as well as to make certain technical and conforming changes related thereto. As a general matter, in the past, when a submitter has not provided sufficient information to identify blocked or unblocked property and to determine the authority or authorities under which it was blocked or unblocked, OFAC has requested follow up information from the submitter, sometimes requiring multiple requests. OFAC is expanding the information listed in § 501.603 that is required to be submitted in reports on blocked property in an effort to clarify what information is needed to reduce the need for follow up requests from OFAC and in order to lessen the overall reporting burden for submitters.

Initial blocking reports. The expanded instructions for initial blocking reports require submitters to include the following information: (1) The name and address of the person holding the blocked property and a contact person from whom additional information may be obtained; (2) a description of any transaction associated with the blocking, including certain identifying information; (3) the associated sanctions target(s) whose property is blocked or a reference to the relevant written communication from OFAC if there is no associated target or that target is unknown; (4) a description of the property that is the subject of the blocking and its location; (5) the date the property was blocked; (6) the actual, or if unknown, estimated value of the property in U.S. Dollars; (7) the legal authority or authorities under which the