Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or

Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine
July 2025

OMB Control No. 0910-0751
Expiration Date: To find the current expiration date, search for this OMB Control No. on the website available at https://www.reginfo.gov.

Table of Contents

I. Introduction

II. Instructions for Submitting Your Attestation Using Form FDA 3942a for Human Food

III. Instructions for Submitting Your Attestation Using Form FDA 3942b for Animal Food

Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or

Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation

I. Introduction

The FDA Food Safety Modernization Act (FSMA) establishes requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans and animals. We have issued two regulations to implement these requirements. The first regulation is established in 21 CFR part 117 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (published in the Federal Register on September 17, 2015, 80 FR 55907). In the remainder of this guidance we refer to this regulation as "part 117." Subparts A, B, and F of part 117 include current good manufacturing practice (CGMP) requirements for manufacturing, processing, packing, or holding human food. Subparts A, C, D, E, F, and G of part 117 include requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements). The second regulation is established in 21 CFR part 507 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (published in the Federal Register on September 17, 2015, 80 FR 56170). In the remainder of this document we refer to this regulation as "part 507." For domestic and foreign facilities that are required to register, subparts A, B, and F of part 507 include CGMP requirements and subparts A, C, D, E, and F of part 507 include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements).

A facility that meets the definition of a "qualified facility" in part 117 or part 507 is subject to modified requirements in 21 CFR 117.201 or in 21 CFR 507.7 respectively. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility. Section II of this document explains how to submit Form FDA 3942a attesting to your facility's status as a qualified facility under part 117. Section III of this document explains how to submit Form FDA 3942b attesting to your facility's status as a qualified facility under part 507.

For additional information about how to determine whether your facility meets the definition of "qualified facility" under part 117 or part 507 and about records you would keep to document

your determination, see our guidance entitled "Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Animal Food: Guidance for Industry" (Ref. 1).

II. Instructions for Submitting Your Attestation Using Form FDA 3942a for Human Food

1. How do I obtain Form FDA 3942a?

You may obtain a copy of Form FDA 3942a by any of the following mechanisms:

Download it from https://www.fda.gov/media/115813/download;

- Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740; or
- Request a copy of Form FDA 3942a by phone at 1-800-216-7331 or 301-575-0156.

2. Who is responsible for providing attestation?

The owner, operator, or agent in charge of the facility ("I" or "you") is responsible for providing attestation on Form FDA 3942a.

3. What do I attest to on Form FDA 3942a?

On Form FDA 3942a, you must make two attestations:

- First, you must attest that, when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

    1. Your facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the business (including any subsidiaries and affiliates) averaged less than $1,000,000, adjusted for inflation, per year, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale; or

    2. Your facility meets the definition of "qualified facility" in 21 CFR 117.3 because:
        a. During the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at your facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by your facility to all other purchasers; and

b. The average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

- Second, you must attest that:

1. You have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

2. Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulation of foreign countries, based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

For additional information about how to determine whether your facility meets the definition of "qualified facility" under part 117 and about records you would keep to document your determination, see our guidance entitled "Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Guidance for Industry" (Ref. 1).

4. How do I fill out Form FDA 3942a?

There are six sections to Form FDA 3942a, and you provide information for each of these parts as follows:

- Section 1: Facility Information. Provide your Facility Registration Number and the name and address of your facility. Provide applicable information about the facility's telephone number, fax number, and email address.
- Section 2: Type of Notification. Indicate whether your submission is an initial submission, biennial (i.e., renewal) submission, or status change from a "qualified facility" to "not a qualified facility."
- Section 3: Qualification for Modified Requirements. Check the applicable box to indicate that your facility satisfies the definition of a qualified facility based on (1) the definition of "very small business"; or (2) the criteria for total sales and value of sales to qualified end-users.
- Section 4: Compliance with 21 CFR 117.201(a)(2). Check the applicable box to indicate that:
    - You have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective (21 CFR 117.201(a)(2)(i)); or

    - Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight (21 CFR 117.201(a)(2)(ii)).
- Section 5: Attestation Statement. Provide your name and contact information, and sign and date the attestation to indicate that:
    - To the best of your knowledge and belief, the information provided in the Qualified Facility Attestation is true, accurate, and complete and that your facility qualifies for the exemption requested;
    - You understand that, as the owner, operator, or agent in charge of the facility, you must maintain those records relied upon to support these attestations (21 CFR 117.201(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.320); and
    - You understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
- Section 6: Status Change. If applicable, check the box to indicate that your facility has changed status from a "qualified facility" to "not a qualified facility" based on the annual determination in 21 CFR 117.201(c)(1).

5. How do I submit Form FDA 3942a?

We encourage electronic submission of Form FDA 3942a, but you can also submit a hard copy by mail or other delivery service:

- Electronic submission. To submit electronically, go to http://www.fda.gov/furls and follow the instructions.

- Submission by mail or other delivery service. Send the completed paper Form FDA 3942a to U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740.

III. Instructions for Submitting Your Attestation Using Form FDA 3942b for Animal Food

1. How do I obtain Form FDA 3942b?

You may obtain a copy of Form FDA 3942b by any of the following mechanisms:

- Download it from https://www.fda.gov/media/115854/download;

- Write to the U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740; or
- Request a copy of Form FDA 3942b by phone at 1-800-216-7331 or 301-575-0156.

2. Who is responsible for providing attestation?

The owner, operator, or agent in charge of the facility ("I" or "you") is responsible for providing attestation on Form FDA 3942b.

3. What do I attest to on Form FDA 3942b?

On Form FDA 3942b, you must make two attestations:

- First, you must attest that, when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively of any entity of which the facility is a subsidiary or affiliate:

    1. Your facility qualifies for the exemption as a "very small business" as defined in 21 CFR 507.3 because, during the preceding three calendar years, the business (including any subsidiaries and affiliates) averaged less than $2.5 million, adjusted for inflation, per year, in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale; or

    2. Your facility meets the definition of "qualified facility" in 21 CFR 507.3 because:
        a. During the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at your facility that was sold directly to qualified end-users (as defined in 21 CFR 507.3) exceeded the average annual monetary value of the food sold by your facility to all other purchasers; and
        b. The average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

- Second, you must attest that:

    1. You have identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

    2. Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulation of foreign countries, based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

For additional information about how to determine whether your facility meets the definition of "qualified facility" under part 507 and about records you would keep to document your determination, see our guidance entitled "Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Guidance for Industry" (Ref. 1).

4. How do I fill out Form FDA 3942b?

There are six sections to Form FDA 3942b, and you provide information for each of these parts as follows:

- Section 1: Facility Information. Provide your Facility Registration Number and the name and address of your facility. Provide applicable information about the facility's telephone number, telefax number, and email address.
- Section 2: Type of Notification. Indicate whether your submission is an initial submission, biennial (i.e., renewal) submission, or status change from a "qualified facility" to "not a qualified facility."
- Section 3: Qualification for Modified Requirements. Check the applicable box to indicate that your facility satisfies the definition of a qualified facility based on (1) the definition of "very small business"; or (2) the criteria for total sales and value of sales to qualified end-users.
- Section 4: Compliance with 21 CFR 507.7(a)(2). Check the applicable box to indicate that:
    - You have identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective (21 CFR 507.7(a)(2)(i)); or
    - Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight (21 CFR 507.7(a)(2)(ii)).
- Section 5: Attestation Statement. Provide your name and contact information, and sign and date the attestation to indicate that:
    - To the best of your knowledge and belief, the information provided in the Qualified Facility Attestation is true, accurate, and complete and that your facility qualifies for the exemption requested;
    - You understand that, as the owner, operator, or agent in charge of the facility, you must maintain those records relied upon to support these attestations (21 CFR 507.7(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 507.200(c)); and

    - You understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.
- Section 6: Status Change. If applicable, check the box to indicate that your facility has changed status from a "qualified facility" to "not a qualified facility" based on the annual determination in 21 CFR 507.7(c)(1).

5. How do I submit Form FDA 3942b?

We encourage electronic submission of Form FDA 3942b, but you can also submit a hard copy by mail or other delivery service:

- Electronic submission. To submit electronically, go to http://www.fda.gov/furls and follow the instructions.
- Submission by mail or other delivery service. Send the completed paper Form FDA 3942b to U.S. Food and Drug Administration (HFS-681), 5001 Campus Drive, College Park, MD 20740.

IV. References

1. FDA. 2018. Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: Guidance for Industry. Available at: https://www.fda.gov/pchfrule and https://www.fda.gov/pcafrule.

Paperwork Reduction Act Statement:

This guidance contains information collection provisions that 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 Paperwork Reduction Act of 1995 provides that an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0751. The time required to complete this information collection is estimated to average 30 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRABranch@fda.hhs.gov.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection is 0910-0751.