

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E—Withdrawal of a Qualified Facility Exemption

§ 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 117.254 Issuance of an order to withdraw a qualified facility exemption.

(a) An FDA Division Director in whose division the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of

Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

[80 FR 56145, Sept. 17, 2015, as amended at 85 FR 16553, Mar. 24, 2020]

§ 117.257 Contents of an order to withdraw a qualified facility exemption.

An order to withdraw a qualified facility exemption under § 117.5(a) must include the following information:

(a) The date of the order;

(b) The name, address, and location of the qualified facility;

(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or

(2) Conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(d) A statement that the facility must either:

(1) Comply with subparts C and G of this part on the date that is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.

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(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in §117.287;

(f) The text of section 418(1) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in §117.270;

(h) The mailing address, telephone number, email address, fax number, and name of the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016; 85 FR 16553, Mar. 24, 2020]

§ 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.

(a) If you receive an order under §117.254 to withdraw a qualified facility exemption, you must either:

(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of §117.264.

(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(c) If you appeal the order, and FDA confirms the order:

(1) You must comply with applicable requirements of this part within 120

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calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) You are no longer subject to the modified requirements in §117.201.

§ 117.264 Procedure for submitting an appeal.

(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA Division Director in whose division the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or fax number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under §117.5(a), you may include a written request for an informal hearing as provided in §117.267.

[80 FR 56145, Sept. 17, 2015, as amended at 81 FR 3716, Jan. 22, 2016; 85 FR 16553, Mar. 24, 2020]

§ 117.267 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with §117.264 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.