and Compliance, CVM, will respond to a petition requesting a waiver.

### § 1.924 What process applies to a petition requesting a waiver?

(a) In general, the procedures set forth in §10.30 of this chapter govern our response to a petition requesting a waiver.

(b) Under §10.30(h)(3) of this chapter, we will publish a notice in the FEDERAL REGISTER, requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.

(c) Under §10.30(e)(3) of this chapter, we will respond to the petitioner in writing.

(1) If we grant the petition, either in whole or in part, we will publish a notice in the FEDERAL REGISTER setting forth any waiver and the reasons for such waiver.

(2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

### § 1.926 Under what circumstances may we deny a petition requesting a waiver?

We may deny a petition requesting a waiver if the petition does not provide the information required under §1.918 (including the requirements of §10.30 of this chapter), or if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or that the waiver could be contrary to the public interest.

### § 1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?

If we, on our own initiative, determine that a waiver is appropriate, we will publish a notice in the FEDERAL REGISTER setting forth the waiver and the reasons for such waiver.

### § 1.930 When will a waiver that we grant become effective?

Any waiver that we grant will become effective on the date that notice of the waiver is published in the FEDERAL REGISTER.

### § 1.932 Under what circumstances may we modify or revoke a waiver?

We may modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest.

### § 1.934 What procedures apply if we determine that a waiver should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.

(2) We will publish a notice of our determination that a waiver should be modified or revoked in the FEDERAL REGISTER. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the FEDERAL REGISTER. The effective date of the decision will be the date of publication of the notice.

## Subpart P [Reserved]

## Subpart Q—Administrative Detention of Drugs Intended for Human or Animal Use

### § 1.980 Administrative detention of drugs.

(a) *General.* This section sets forth the procedures for detention of drugs believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of drugs encountered during inspections that may

be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the drugs, and to initiate legal action, if appropriate. Drugs that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) *Criteria for ordering detention.* Administrative detention of drugs may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act, has reason to believe that a drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act, is adulterated or misbranded.

(c) *Detention period.* The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless the FDA Division Director in whose division the drugs are located determines that a greater period is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action, in which case the Division Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(d) *Issuance of detention order.* (1) The detention order must be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the drugs are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the drugs are located. If the owner or the user of the drugs is different from the owner, operator, or agent in charge of the place where the drugs are detained, a copy of the detention order must be provided to the owner or user of the drugs if the owner's or user's identity can be readily determined.

(2) If detention of drugs in a vehicle or other carrier is ordered, a copy of the detention order must be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order must include the following information:

(i) A statement that the drugs identified in the order are detained for the period shown;

(ii) A brief, general statement of the reasons for the detention;

(iii) The location of the drugs;

(iv) A statement that these drugs are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative;

(v) Identification of the detained drugs;

(vi) The detention order number;

(vii) The date and hour of the detention order;

(viii) The period of the detention;

(ix) The text of section 304(g) of the Federal Food, Drug, and Cosmetic Act and paragraphs (g)(1) and (g)(2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and

(xi) The mailing address, telephone number, and name of the FDA Division Director.

(e) *Approval of detention order.* A detention order, before issuance, must be approved by the FDA Division Director in whose division the drugs are located. If prior written approval is not feasible, prior oral approval must be obtained and confirmed by written memorandum within FDA as soon as possible.

(f) *Labeling or marking a detained drug.* An FDA representative issuing a detention order under paragraph (d) of this section must label or mark the drugs with official FDA tags that include the following information:

(1) A statement that the drugs are detained by the U.S. Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the drugs must not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of the tag is punishable by fine or imprisonment or both (section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) *Appeal of a detention order.* (1) A person who would be entitled to claim the drugs, if seized, may appeal a detention order. Any appeal must be submitted in writing to the FDA Division Director in whose division the drugs are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 201(x) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(x)), the appellant must request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which must not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order must state the ownership or proprietary interest the appellant has in the detained drugs. If the detained drugs are located at a place other than an establishment owned or operated by the appellant, the appellant must include documents showing that the appellant would have legitimate authority to claim the drugs if seized.

(3) Any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that:

(i) The detention order under paragraph (d) of this section, rather than the notice under §16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under §16.80(a) of this chapter;

(ii) A request for a hearing under this section should be addressed to the FDA Division Director;

(iii) The last sentence of §16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section;

(iv) Paragraph (g)(4) of this section, rather than §16.42(a) of this chapter, describes the FDA employees who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also must decide the appeal, must be an Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director who is permitted by §16.42(a) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer must, within 5 working days, hold the hearing and render a decision affirming or revoking the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer must hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer must decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the detention order but does not request a regulatory hearing, the presiding officer must render a decision on the appeal, affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the drugs continue to be detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(9) If the presiding officer revokes a detention order, FDA must terminate the detention under paragraph (j) of this section.

(h) *Movement of detained drugs.* (1) Except as provided in this paragraph, no person may move detained drugs within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(2) If detained drugs are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the drugs are moved for the purpose in the preceding sentence, the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the drugs. As soon as the drugs are put in final form, they must be segregated from other drugs, and the individual responsible for their movement must orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The drugs put in final form must not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible division office official, may approve, in writing, the movement of detained drugs for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the drugs;

(ii) To destroy the drugs;

(iii) To bring the drugs into compliance;

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible division office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained drugs under paragraph (h)(3) of this section, the detained drugs must remain segregated from other drugs and the person responsible for their movement must immediately orally notify the official who approved the movement of the drugs, or another responsible FDA division office official, of the new location of the detained drugs.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of drugs under this paragraph, the required tags must accompany the drugs during and after movement and must remain with the drugs until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) *Actions involving adulterated or misbranded drugs.* If FDA determines that the detained drugs, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the drugs or the responsible individuals, or both, or request that the drugs be destroyed or otherwise brought into compliance with the Federal Food, Drug, and Cosmetic Act under FDA's supervision.

(j) *Detention termination.* If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the drugs to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) *Recordkeeping requirements.* (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent in charge of any factory, warehouse, other establishment, or consulting laboratory where detained drugs are manufactured, processed, packed, or held, must

have, or establish, and maintain adequate records relating to how the detained drugs may have become adulterated or misbranded, records on any distribution of the drugs before and after the detention period, records on the correlation of any in-process detained drugs that are put in final form under paragraph (h) of this section to the completed drugs, records of any changes in, or processing of, the drugs permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph must be provided to FDA on request for review and copying. Any FDA request for access to records required under this paragraph must be made at a reasonable time, must state the reason or purpose for the request, and must identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph must be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the Agency determines that the drugs are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in part 211 of this chapter).

[79 FR 30719, May 29, 2014, as amended at 82 FR 14144, Mar. 17, 2017; 85 FR 16551, Mar. 24, 2020]

## Subpart R—Laboratory Accreditation for Analyses of Foods

SOURCE: 86 FR 68817, Dec. 3, 2021; 87 FR 5660, Feb. 2, 2022, unless otherwise noted.

GENERAL PROVISIONS

### § 1.1101 What documents are incorporated by reference in this subpart

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the source listed elsewhere in this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; Telephone 41 22 749 01 11, *https://www.iso.org/home.html*.

(1) ISO/IEC 17011:2017(E), Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, Second edition, November 2017, IBR approved for §§ 1.1113(a) and (c), 1.1114(b), 1.1120(c), 1.1131(a).

(2) ISO/IEC 17025:2017(E), General requirements for the competence of testing and calibration laboratories, Third edition, November 2017, IBR approved for §§ 1.1120(c), 1.1121(a), 1.1138(a), 1.1139(b) and (c), 1.1141(a), 1.1152(a) and (d), 1.1153(c), and 1.1161(a).

### § 1.1102 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart, unless otherwise specified. For the purposes of this subpart, the following definitions also apply:

*Analyst* means an individual who analyzes samples.

*Corrective action* means an action taken by an accreditation body or laboratory to investigate and eliminate the cause of a deficiency so that it does not recur.