SUBCHAPTER H—MEDICAL DEVICES

PART 800—GENERAL

Subpart A [Reserved]

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Subpart A [Reserved]

Subpart B—Requirements for Specific Medical Devices

§ 800.10 Contact lens solutions; sterility.

(a)(1) Informed medical opinion is in agreement that all preparations offered or intended for ophthalmic use, including contact lens solutions, should be sterile. It is further evident that such preparations purport to be of such purity and quality as to be suitable for safe use in the eye.

(2) The Food and Drug Administration concludes that all such preparations, if they are not sterile, fall below their professed standard of purity or quality and may be unsafe. In a statement of policy issued on September 1, 1964, the Food and Drug Administration ruled that liquid preparations offered or intended for ophthalmic use that are not sterile may be regarded as adulterated within the meaning of section 501(c) of the Federal Food, Drug, and Cosmetic Act (the act), and, further, may be deemed misbranded within the meaning of section 502(j) of the act. By this regulation, this ruling is applicable to all preparations for ophthalmic use that are regulated as medical devices, i.e., contact lens solutions. By the regulation in § 200.50 of this chapter, this ruling is applicable to ophthalmic preparations that are regulated as drugs.

(3) The containers shall be sterile at the time of filling and closing, and the container or individual carton shall be so sealed that the contents cannot be used without destroying the seal. The packaging and labeling of these solutions shall also comply with § 800.12 on tamper-resistant packaging requirements.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should:

(1) Contain one or more suitable and harmless substances that will inhibit the growth of microorganisms; or

(2) Be so packaged as to volume and type of container and so labeled as to duration of use and with such necessary warnings as to afford adequate protection and minimize the hazard of injury resulting from contamination during use.

(c) Eye cups, eye droppers, and other dispensers intended for ophthalmic use should be sterile, and may be regarded as falling below their professed standard of purity or quality if they are not sterile. These articles, which are regulated as medical devices unless packaged with the drugs with which they are to be used, should be packaged so as to maintain sterility until the package is opened and be labeled, on or within the retail package, so as to afford adequate directions and necessary warnings to minimize the hazard of injury resulting from contamination during use.

[47 FR 50455, Nov. 5, 1982]

§ 800.12 Contact lens solutions and tablets; tamper-resistant packaging.

(a) *General.* Unless contact lens solutions used, for example, to clean, disinfect, wet, lubricate, rinse, soak, or store contact lenses and salt tablets or other dosage forms to be used to make any such solutions are packaged in tamper-resistant retail packages, there

is the opportunity for the malicious adulteration of these products with risks both to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of the packages of over-the-counter (OTC) health care products. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national standard for tamper-resistant packaging of those OTC products vulnerable to malicious adulteration that will improve the security of OTC packaging and help assure the safety and effectiveness of the products contained therein. A contact lens solution or tablet or other dosage form to be used to make such a solution for retail sale that is not packaged in a tamper-resistant package and labeled in accordance with this section is adulterated under section 501 of the act or misbranded under section 502 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages for retail sale a product regulated as a medical device that is a solution intended for use with contact lenses, e.g., for cleaning, disinfecting, wetting, lubricating, rinsing, soaking, or storing contact lenses or tablets or other dosage forms to be used to make any such solution shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term ''distinctive by design'' means the package cannot be duplicated with commonly available material or through commonly available processes. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a product covered by this section is required to bear a statement that is prominently placed so that consumers are alerted to the tamper-resistant feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say ''For your protection, this bottle has an imprinted seal around the neck.''

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under §10.30 of this chapter and should be clearly identified on the envelope as a ''Request for Exemption from Tamper-resistant Rule.'' A petition for an exemption from a requirement of this section is required to contain the same kind of information about the product as is specified for OTC drugs in §211.132(d) of this chapter.

(e) *Products subject to approved premarket approval applications.* Holders of approved premarket approval applications for products subject to this section are required to submit supplements to provide for changes in packaging to comply with the requirement of paragraph (b) of this section unless these changes do not affect the composition of the container, the torque (tightness) of the container, or the composition of the closure component in contact with the contents (cap liner

or innerseal) as these features are described in the approved premarket approval application. Any supplemental premarket approval application under this paragraph is required to include data sufficient to show that these changes do not adversely affect the product.

(f) *Effective date.* Each product subject to this section is required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or labeling requirement:

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on February 7, 1983 for each contact lens solution packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each tablet that is to be used to make a contact lens solution and that is packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each product subject to this section packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected product subject to this section packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective on February 6, 1984 for each product subject to this section that is held for sale at retail level on or after that date that was packaged for retail sale before May 5, 1983. This does not include the requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, are required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

[47 FR 50455, Nov. 5, 1982; 48 FR 1706, Jan. 14, 1983, as amended at 48 FR 16666, Apr. 19, 1983; 48 FR 37625, Aug. 19, 1983; 53 FR 11252, Apr. 6, 1988; 73 FR 34859, June 19, 2008]

EFFECTIVE DATE NOTE: A document published at 48 FR 41579, Sept. 16, 1983, stayed the effective date of § 800.12(f)(3) until further notice.

§ 800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration.

(a) *Purpose.* The prevalence of human immunodeficiency virus (HIV), which causes acquired immune deficiency syndrome (AIDS), and its risk of transmission in the health care context, have caused the Food and Drug Administration (FDA) to look more closely at the quality control of barrier devices, such as surgeons' gloves and patient examination gloves (collectively known as medical gloves) to reduce the risk of transmission of HIV and other blood-borne infectious diseases. The Centers for Disease Control (CDC) recommend that health care workers wear medical gloves to reduce the risk of transmission of HIV and other blood-borne infectious deseases. The CDC recommends that health care workers wear medical gloves when touching blood or other body fluids, mucous membranes, or nonintact skin of all patients; when handling items or surfaces soiled with blood or other body fluids; and when performing venipuncture and other vascular access procedures. Among other things, CDC's recommendation that health care providers wear medical gloves demonstrates the proposition that devices labeled as medical gloves purport to be and are represented to be effective barriers against the transmission of blood- and fluid-borne pathogens. Therefore, FDA, through this regulation, is defining adulteration for patient examination and surgeons' gloves as a means of assuring safe and effective devices.

(1) For a description of a patient examination glove, see § 880.6250. Finger cots, however, are excluded from the

test method and sample plans in paragraphs (b) and (c) of this section.

(2) For a description of a surgeons' glove, see § 878.4460 of this chapter.

(b)(1) *General test method.* For the purposes of this part, FDA's analysis of gloves for leaks and visual defects will be conducted by a visual examination and by a water leak test method, using 1,000 milliliters (ml) of water.

(i) *Units examined.* Each medical glove will be analyzed independently. When packaged as pairs, each glove is considered separately, and both gloves will be analyzed.

(ii) *Identification of defects.* For this test, defects include leaks detected when tested in accordance with paragraph (b)(3) of this section. A leak is defined as the appearance of water on the outside of the glove. This emergence of water from the glove constitutes a watertight barrier failure. Other defects include tears, embedded foreign objects, extrusions of glove material on the exterior or interior surface of the glove, gloves that are fused together so that individual glove separation is impossible, gloves that adhere to each other and tear when separated, or other visual defects that are likely to affect the barrier integrity.

(iii) *Factors for counting defects.* One defect in one glove is counted as one defect. A defect in both gloves in a pair of gloves is counted as two defects. If multiple defects, as defined in paragraph (b)(1)(ii) of this section, are found in one glove, they are counted as one defect. Visual defects and leaks that are observed in the top 40 millimeters (mm) of a glove will not be counted as a defect for the purposes of this part.

(2) *Leak test materials.* FDA considers the following to be the minimum materials required for this test :

(i) A 60 mm by 380 mm (clear) plastic cylinder with a hook on one end and a mark scored 40 mm from the other end (a cylinder of another size may be used if it accommodates both cuff diameter and any water above the glove capacity);

(ii) Elastic strapping with velcro or other fastening material;

(iii) Automatic water-dispensing apparatus or manual device capable of delivering 1,000 ml of water;

(iv) Stand with horizontal rod for hanging the hook end of the plastic tube. The horizontal support rod must be capable of holding the weight of the total number of gloves that will be suspended at any one time, e.g., five gloves suspended will weigh about 5 kilograms (kg);

(v) Timer capable of measuring two minute intervals.

(3) *Visual defects and leak test procedures.* Examine the sample and identify code/lot number, size, and brand as appropriate. Continue the visual examination using the following procedures:

(i) *Visual defects examination.* Inspect the gloves for visual defects by carefully removing the glove from the wrapper, box, or package. Visually examine each glove for defects. As noted in paragraph (b)(1)(iii) of this section, a visual defect observed in the top 40 mm of a glove will not be counted as a defect for the purpose of this part. Visually defective gloves do not require further testing, although they must be included in the total number of defective gloves counted for the sample.

(ii) *Leak test set-up.* (A) During this procedure, ensure that the exterior of the glove remains dry. Attach the glove to the plastic fill tube by bringing the cuff end to the 40 mm mark and fastening with elastic strapping to make a watertight seal.

(B) Add 1,000 ml of room temperature water (i.e., 20 (deg)C to 30 (deg)C) into the open end of the fill tube. The water should pass freely into the glove. (With some larger sizes of long-cuffed surgeons' gloves, the water level may reach only the base of the thumb. With some smaller gloves, the water level may extend several inches up the fill tube.)

(iii) *Leak test examination.* Immediately after adding the water, examine the glove for water leaks. Do not squeeze the glove; use only minimum manipulation to spread the fingers to check for leaks. Water drops may be blotted to confirm leaking.

(A) If the glove does not leak immediately, keep the glove/filling tube assembly upright and hang the assembly vertically from the horizontal rod, using the wire hook on the open end of the fill tube (do not support the filled glove while transferring).

(B) Make a second observation for leaks 2 minutes after the water is added to the glove. Use only minimum manipulation of the fingers to check for leaks.

(C) Record the number of defective gloves.

(c) *Sampling, inspection, acceptance, and adulteration.* In performing the test for leaks and other visual defects described in paragraph (b) of this section, FDA will collect and inspect samples of medical gloves, and determine when the gloves are acceptable as set out in paragraphs (c)(1) through (c)(3) of this section.

(1) *Sample plans.* FDA will collect samples from lots of medical gloves in accordance with agency sampling plans. These plans are based on sample sizes, levels of sample inspection, and acceptable quality levels (AQLs) found in the International Standard Organization's standard ISO 2859, ''Sampling Procedures For Inspection By Attributes.''

(2) *Sample sizes, inspection levels, and minimum AQLs.* FDA will use single normal sampling for lots of 1,200 gloves or less and multiple normal sampling for all larger lots. FDA will use general inspection level II in determining the sample size for any lot size. As shown in the tables following paragraph (c)(3) of this section, FDA considers a 1.5 AQL to be the minimum level of quality acceptable for surgeons' gloves and a 2.5 AQL to be the minimum level of quality acceptable for patient examination gloves.

(3) *Adulteration levels and accept/reject criteria.* FDA considers a lot of medical gloves to be adulterated when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number at the 1.5 AQL for surgeons' gloves or the 2.5 AQL for patient examination gloves. These acceptance and rejection numbers are identified in the tables following paragraph (c)(3) of this section as follows:

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR SURGEONS' GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
8 to 90	Single sample		8	0	1
91 to 280	Single sample		32	1	2
281 to 500	Single sample		50	2	3
501 to 1,200	Single sample		80	3	4
1,201 to 3,200	First	32	32	—	4
	Second	32	64	1	5
	Third	32	96	2	6
	Fourth	32	128	3	7
	Fifth	32	160	5	8
	Sixth	32	192	7	9
	Seventh	32	224	9	10
3,201 to 10,000	First	50	50	0	4
	Second	50	100	1	6
	Third	50	150	3	8
	Fourth	50	200	5	10
	Fifth	50	250	7	11
	Sixth	50	300	10	12
	Seventh	50	350	13	14
10,001 to 35,000	First	80	80	0	5
	Second	80	160	3	8
	Third	80	240	6	10
	Fourth	80	320	8	13
	Fifth	80	400	11	15
	Sixth	80	480	14	17
	Seventh	80	560	18	19
35,000	First	125	125	1	7
	Second	125	250	4	10
	Third	125	375	8	13
	Fourth	125	500	12	17
	Fifth	125	625	17	20

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR SURGEONS' GLOVES—Continued

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
	Sixth	125	750	21	23
	Seventh	125	875	25	26

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR PATIENT EXAMINATION GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
5 to 50	Single sample		5	0	1
51 to 150	Single sample		20	1	2
151 to 280	Single sample		32	2	3
281 to 500	Single sample		50	3	4
501 to 1,200	Single sample		80	5	6
1,201 to 3,200	First	32	32	0	4
	Second	32	64	1	6
	Third	32	96	3	8
	Fourth	32	128	5	10
	Fifth	32	160	7	11
	Sixth	32	192	10	12
	Seventh	32	224	13	14
3,201 to 10,000	First	50	50	0	5
	Second	50	100	3	8
	Third	50	150	6	10
	Fourth	50	200	8	13
	Fifth	50	250	11	15
	Sixth	50	300	14	17
	Seventh	50	350	18	19
10,001 to 35,000	First	80	80	1	7
	Second	80	160	4	10
	Third	80	240	8	13
	Fourth	80	320	12	17
	Fifth	80	400	17	20
	Sixth	80	480	21	23
	Seventh	80	560	25	26
35,000 and above	First	125	125	2	9
	Second	125	250	7	14
	Third	125	375	13	19
	Fourth	125	500	19	25
	Fifth	125	625	25	29
	Sixth	125	750	31	33
	Seventh	125	875	37	38

(d) *Compliance.* Lots of gloves that are sampled, tested, and rejected using procedures in paragraphs (b) and (c) of this section, are considered adulterated within the meaning of section 501(c) of the act.

(1) *Detention and seizure.* Lots of gloves that are adulterated under section 501(c) of the act are subject to administrative and judicial action, such as detention of imported products and seizure of domestic products.

(2) *Reconditioning.* FDA may authorize the owner of the product, or the owner's representative, to attempt to recondition, i.e., bring into compliance with the act, a lot or part of a lot of foreign gloves detained at importation, or a lot or part of a lot of seized domestic gloves.

(i) *Modified sampling, inspection, and acceptance.* If FDA authorizes reconditioning of a lot or portion of a lot of adulterated gloves, testing to confirm that the reconditioned gloves meet

AQLs must be performed by an independent testing facility. The following tightened sampling plan must be followed, as described in ISO 2859 ''Sampling Procedures for Inspection by Attributes:''

(A) General inspection level II,

(B) Single sampling plans for tightened inspection,

(C) 1.5 AQL for surgeons' gloves, and

(D) 2.5 AQL for patient examination gloves.

(ii) *Adulteration levels and acceptance criteria for reconditioned gloves.* (A) FDA considers a lot or part of a lot of adulterated gloves, that is reconditioned in accordance with paragraph (d)(2)(i) of this section, to be acceptable when the number of defective gloves found in the tested sample does not exceed the acceptance number in the appropriate tables in paragraph (d)(2)(ii)(B) of this section for reconditioned surgeons' gloves or patient examination gloves.

(B) FDA considers a reconditioned lot of medical gloves to be adulterated within the meaning of section 501(c) of the act when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number in the tables following paragraph (d)(2)(ii)(B) of this section:

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR RECONDITIONED SURGEONS' GLOVES

Lot Size	Sample	Sample Size	Number Defective	
			Accept	Reject
13 to 90	Single sample	13	0	1
91 to 500	Single sample	50	1	2
501 to 1,200	Single sample	80	2	3
1,201 to 3,200	Single sample	125	3	4
3,201 to 10,000	Single sample	200	5	6
10,001 to 35,000	Single sample	315	8	9
35,000 and above	Single sample	500	12	13

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR RECONDITIONED PATIENT EXAMINATION GLOVES

Lot Size	Sample	Sample Size	Number Defective	
			Accept	Reject
8 to 50	Single sample	8	0	1
51 to 280	Single sample	32	1	2
281 to 500	Single sample	50	2	3
501 to 1,200	Single sample	80	3	4
1,201 to 3,200	Single sample	125	5	6
3,201 to 10,000	Single sample	200	8	9
10,001 to 35,000	Single sample	315	12	13
35,000 and above	Single sample	500	18	19

[55 FR 51256, Dec. 12, 1990, as amended at 71 FR 75876, Dec. 19, 2006]

Subpart C—Administrative Practices and Procedures

§ 800.55 Administrative detention.

(a) *General.* This section sets forth the procedures for detention of medical devices intended for human use believed to be adulterated or misbranded.

Administrative detention is intended to protect the public by preventing distribution or use of devices 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 devices, and to initiate legal action, if appropriate. Devices 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 devices 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 (the act), has reason to believe that a device, as defined in section 201(h) of the 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 devices are located determines that a greater period is required to seize the devices, 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 shall be issued in writing, in the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the devices are adulterated or misbranded, and issued to the owner, operator, or agent in charge of the place where the devices are located. If the owner or the user of the devices is different from the owner, operator, or agent in charge of the place where the devices are detained, a copy of the detention order shall be provided to the owner or user of the devices if the owner's or user's identity can be readily determined.

(2) If detention of devices in a vehicle or other carrier is ordered, a copy of the detention order shall 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 shall include the following information:

(i) A statement that the devices 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 devices;

(iv) A statement that these devices 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 devices;

(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 act and paragraph (g) (1) and (2) of this section;

(x) A statement that any informal hearing on an appeal of a detention order shall 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, shall be approved by the FDA Division Director in whose division the devices are located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written

memorandum within FDA as soon as possible.

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

(1) A statement that the devices are detained by the United States 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 devices shall 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 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 devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to the FDA Division Director in whose division the devices 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 act, the appellant shall 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 shall not be later than 20 calendar days after receipt of a detention order.

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

(3) Any informal hearing on an appeal of a detention order shall be conducted as a regulatory hearing pursuant to 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 shall decide the appeal, shall 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 shall, 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 shall hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer shall 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 shall 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 devices 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 shall terminate the detention under paragraph (j) of this section.

(h) *Movement of detained devices.* (1) Except as provided in this paragraph (h), no person shall move detained devices 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 devices 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 devices are moved for the purpose of the preceding sentence, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible division office official, of their new location. The devices put in final form shall 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 devices for any of the following purposes:

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

(ii) To destroy the devices.

(iii) To bring the devices 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 devices under paragraph (h)(3) of this section, the detained devices shall remain segregated from other devices and the person responsible for their movement shall immediately orally notify the official who approved the movement of the devices, or another responsible FDA division office official, of the new location of the detained devices.

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

(i) *Actions involving adulterated or misbranded devices.* If FDA determines that the detained devices, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal action against the devices or the responsible individuals, or both, or request that the devices be destroyed or otherwise brought into compliance with the 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 devices 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 devices are manufactured, processed, packed, or held shall

have, or establish, and maintain adequate records relating to how the detained devices may have become adulterated or misbranded, records on any distribution of the devices before and after the detention period, records on the correlation of any in-process detained devices that are put in final form under paragraph (h) of this section to the completed devices, records of any changes in, or processing of, the devices permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph shall be provided to the FDA on request for review and copying. Any FDA request for access to records required under this paragraph shall be made at a reasonable time, shall state the reason or purpose for the request, and shall 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 shall 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 devices 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 820 of this chapter).

[44 FR 13239, Mar. 9, 1979, as amended at 49 FR 3174, Jan. 26, 1984; 69 FR 17292, Apr. 2, 2004; 79 FR 9412, Feb. 19, 2014; 82 FR 14147, Mar. 17, 2017; 85 FR 16555, Mar. 25, 2020]

§ 800.75 Requests for supervisory review of certain decisions made by the Center for Devices and Radiological Health.

(a) *Definitions.* The following definitions shall apply to this section:

(1) *FDA* means the Food and Drug Administration.

(2) *517A decision* means a significant decision made by the Center for Devices and Radiological Health, as set forth in section 517A of the Federal Food, Drug, and Cosmetic Act, and includes one of the following decisions:

(i) A substantially equivalent order under § 807.100(a)(1) of this chapter, or a not substantially equivalent order under § 807.100(a)(2) of this chapter;

(ii) An approval order under § 814.44(d) of this chapter, an approvable letter under § 814.44(e) of this chapter, a not approvable letter under § 814.44(f) of this chapter, or an order denying approval under § 814.45 of this chapter;

(iii) An approval order under § 814.116(b) of this chapter, an approvable letter under § 814.116(c) of this chapter, a not approvable letter under § 814.116(d) of this chapter, or an order denying approval under § 814.118 of this chapter;

(iv) A grant or denial of a request for breakthrough device designation under section 515B of the Federal Food, Drug, and Cosmetic Act;

(v) An approval order under § 812.30(a) of this chapter or a disapproval order under § 812.30(c) of this chapter;

(vi) A failure to reach agreement letter under section 520(g)(7) of the Federal Food, Drug, and Cosmetic Act; or

(vii) A clinical hold determination under section 520(g)(8) of the Federal Food, Drug, and Cosmetic Act.

(3) *CDRH* means the Center for Devices and Radiological Health.

(b) *Submission of request*—(1) *Review of 517A decisions.* (i) An initial or sequential request for supervisory review within CDRH of a 517A decision under § 10.75 of this chapter must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act; marked ''Appeal: Request for Supervisory Review''; and received by CDRH no later than 30 days after the date of the decision involved. Any such request for supervisory review not received by CDRH within 30 days after the date of the decision involved is not eligible for review. Except as provided in paragraph (b)(1)(ii) or

(iii) of this section, FDA will render a decision within 45 days of the request for supervisory review.

(ii) A person requesting supervisory review under paragraph (b)(1)(i) may request an in-person meeting or teleconference with the supervisor reviewing the request for supervisory review. Except as provided in paragraph (b)(1)(iii) of this section, if a request for in-person meeting or teleconference is included in the request for supervisory review to CDRH, CDRH will schedule the meeting or teleconference to occur within 30 days of receipt of the request. Except as provided in paragraph (b)(1)(iii) of this section, a decision will be rendered within 30 days of such meeting or teleconference.

(iii) The timeframes for CDRH to render a decision provided in (b)(1)(i) and (ii) of this section, and the timeframe to schedule an in-person meeting or teleconference review in (b)(1)(ii) of this section, do not apply if a matter related to the 517A decision under review is referred by CDRH to external experts, such as an advisory committee, as provided in §10.75(b) of this chapter.

(2) *Supervisory review.* An initial or sequential request for supervisory review within CDRH under §10.75 of this chapter of a decision other than a 517A decision that is not received by CDRH within 60 days after the date of the decision involved will be denied as untimely, unless CDRH, for good cause, permits the request to be filed after 60 days. An initial or sequential request for supervisory review within CDRH of a decision other than a 517A decision must be addressed to the next organizational level or higher above the individual who made the decision; submitted in electronic format in accordance with section 745A(b) of the Federal Food, Drug, and Cosmetic Act, when applicable; marked, ''Appeal: Request for Supervisory Review'' in the subject line of the electronic request; and sent to the CDRH Ombudsman at *CDRHOmbudsman@fda.hhs.gov*.

[84 FR 31477, July 2, 2019]

PART 801—LABELING

Subpart A—General Labeling Provisions

Sec.

Subpart B—Labeling Requirements for Unique Device Identification

Subpart C—Labeling Requirements for Over-the-Counter Devices

Subpart D—Exemptions From Adequate Directions for Use