SUBCHAPTER H—MEDICAL DEVICES

PART 800—GENERAL

Subpart A [Reserved]

Subpart B—Requirements for Specific Medical Devices

Subpart C—Administrative Practices and Procedures

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Section 800.30 also issued under Sec. 709, Pub. L. 115–52, 131 Stat. 1065–67.

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

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

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
	Third	125	375	8	13
	Fourth	125	500	12	17
	Fifth	125	625	17	20
	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]

§ 800.30 Over-the-counter hearing aid controls.

(a) *Scope.* This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-

conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered ''available'' over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act or do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation in part 874 of this chapter.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and Cosmetic Act, is not a ''licensed person'' solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a ''licensed person'' solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Rebuilt hearing aid. An OTC hearing aid is ''rebuilt'' if the manufacturer has inspected and tested the device, made any necessary modifications to ensure it meets applicable regulatory requirements, including the requirements in this section to be available OTC, and adequately reprocessed the device for the next user.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs.

Used hearing aid. A hearing aid is ''used'' if a user has worn it for any period of time. However, a hearing aid shall not be ''used'' merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is ''bona fide'' if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* An OTC hearing aid shall bear all of the following in the labeling:

(1) *Outside package labeling.* The outside package of an OTC hearing aid shall bear all of the following:

(i) *Warnings and other important information.* All of the following shall appear on the outside package:

(A) (A) *Warning against use in people younger than 18.*

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) *Symptoms suggesting perceived mild to moderate hearing loss.*

This hearing aid is for adults with signs of mild to moderate hearing loss. How do you know if you have this?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

(C) *Advice of availability of professional services.*

Some people with hearing loss may need help from a hearing healthcare professional. How do you know if you need to see one?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things

If your hearing loss makes it hard to hear loud noises, this hearing aid may not be your best choice without help from a professional. If this hearing aid does not help you enough, ask for help from a hearing healthcare professional.

(D) *''Red flag'' conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(E) *Notice of contact information.*

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] or write to [email address] or [postal address] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.*

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

(ii) *Statement of build condition.* If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(iii) *Statement of OTC availability.* The principal display panel shall bear the marks ''OTC'' and ''hearing aid'' with the same prominence required under § 801.61(c) of this chapter for the device's statement of identity. The device's common name on the principal display panel may satisfy all or part of this requirement to the extent the common name includes the marks.

(iv) *Indication of battery information.* The outside package shall indicate the type and number of batteries and whether batteries are included in the package.

(v) *Indication of control platform.* The outside package shall indicate whether a mobile device or other non-included

control platform is required. The indication must include the type of platform and how the platform connects to the device.

(2) *Labeling, inside the package.* The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18.*

WARNING: If you are younger than 18, do not use this.
You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

(B) *''Red flag'' conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(C) *Warning about pain from device placement.*

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

(ii) Any additional warnings the manufacturer may include prior to the cautions and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following cautions and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

(A) *Caution about hearing protection.*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

(B) *Caution about excessive sound output.*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

(C) *Caution about components lodging in ear.*

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

(D) *Advice to seek professional services.*

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(E) *Note about user expectations.*

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

(iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(v) Information on the function of all controls intended for user adjustment.

(vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.

(vii) Specific instructions for all of the following:

(A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the depth limit and damage to the tympanic membrane.

(B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-selection and self-checking the performance of the OTC hearing aid, and customize it to

the user's hearing needs, including information about properly fitting eartips.

(C) Use of the OTC hearing aid with any accompanying accessories.

(D) Maintenance and care of the OTC hearing aid, including how a lay user can clean, disinfect, and replace parts or how to seek replacements, as well as how to store the hearing aid when it will not be used for an extended period of time.

(E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5 of this chapter.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, referring to an ear-nose-throat doctor when preferable, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to, as applicable, ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) Information on how and where to obtain repair service or replacements, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service or replacements.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

(3) *Labeling on the device*. The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a ''+'' symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications*. All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package:

(i) The maximum output limit value (Output Sound Pressure Level 90 (OSPL90)).

(ii) The full-on gain value, which is the gain with a 50 decibel (dB) Sound Pressure Level (SPL) pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(5) *Software device labeling*. OTC hearing aid software that is not distributed with the hearing aid or amplification platform shall meet all of the following labeling requirements. With respect to the information required under paragraphs (c)(1) through (4) of this section, the information must be provided in the software device labeling, as specified in paragraphs (c)(5)(i) through (v) of this section, rather than the locations (*e.g.*, outside package labeling) specified in paragraphs (c)(1) through (4):

(i) Prior to first use of the software or obtaining payment information for the software, whichever occurs first, the labeling must clearly and prominently present all of the following to the prospective user. For each, the labeling must remain visible until the user dismisses it or proceeds to the next step:

(A) Compatibility and minimum operating requirements for the software device.

(B) Disclosures of any fees or payments after first use or initial payment, including but not limited to any fees or payments relating to subscriptions, add-on features, or continued access to features or services. The disclosures must name and briefly describe what each fee or payment covers.

(C) The information required under paragraphs (c)(1)(i), (iii), and (v) of this section.

(ii) Prior to first use of the software, the labeling must clearly and prominently present all of the following to the prospective user:

(A) The information required under paragraph (c)(2)(i)(A) of this section, and it must remain visible until the user acknowledges it.

(B) The information required under paragraphs (c)(2)(i)(B) and (C), (c)(2)(ii), (iii), and (v), (c)(2)(vii)(B) and (G), and (c)(2)(viii) and (ix) of this section, and the information must remain visible until the user dismisses it or proceeds to the next step.

(C) All other information required under paragraph (c)(2) of this section, to the extent applicable, and the information must remain visible until the user dismisses it or proceeds to the next step.

(iii) The software device labeling must include the information required under paragraphs (c)(3)(i) and (c)(4) of this section.

(iv) All of the software device labeling must be accessible for review after acknowledgment, dismissal, or proceeding to the next step.

(v) If there are changes to any of the labeling required under paragraph (c)(5) of this section, the labeling with the changed information must be presented to the user until the user dismisses it.

(d) *Output limits.* The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) with an acoustic coupler as described in paragraph (e)(6) of this section when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits at any of the frequencies at which the device is intended to operate:

(1) *General output limit.* An OTC hearing aid shall not exceed an output limit of 111 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) *Output limit for a device with activated input-controlled compression.* An OTC hearing aid that has input-controlled compression activated shall not exceed an output limit of 117 dB SPL at any frequency.

(e) *Electroacoustic performance limits.* An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using an acoustic coupler as described in paragraph (e)(6) of this section, where applicable:

(1) *Output distortion control limits.* Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-hertz (Hz) one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) *Self-generated noise level limits.* Self-generated noise shall not exceed 32 dBA. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) *Latency.* Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) *Frequency response bandwidth.* The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff

frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(5) *Frequency response smoothness.* No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(6) *Acoustic coupler choice.* Where applicable, use one of the following acoustic couplers to measure electroacoustic performance:

(i) When compatible with the device design, a 2-cubic centimeter (cm^3) acoustic coupler; or

(ii) When a 2-cm^3 acoustic coupler is not compatible with the device design, an acoustic coupler that is a scientifically valid and technically equivalent alternative. You must document the rationale for using an alternative acoustic coupler.

(f) *Design requirements.* An OTC hearing aid must conform to all of the following design requirements:

(1) *Insertion depth.* The design of an OTC hearing aid shall limit the insertion of the most medial component so that, when inserted, the component is reasonably expected to remain at least 10 millimeters (mm) from the tympanic membrane.

(2) *Use of atraumatic materials.* The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) *Proper physical fit.* The design of an OTC hearing aid shall enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) *Tools, tests, or software.* The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(5) *User-adjustable volume control.* The OTC hearing aid shall have a user-adjustable volume control.

(6) *Adequate reprocessing.* If the OTC hearing aid is used or rebuilt, it must be adequately reprocessed for the next user prior to sale.

(g) *Conditions for sale of an OTC hearing aid.* The sale of an OTC hearing aid is subject to all of the following conditions:

(1) *Age minimum.* Sale to or for a person younger than 18 years of age is prohibited.

(2) *Statement of OTC availability.* Sale of an OTC hearing aid is prohibited unless its labeling bears the statement of OTC availability required under paragraph (c)(1)(iii) of this section.

(h) *Effect on State law.* Any State or local government requirement for an OTC hearing aid is preempted to the following extent:

(1) *Preemption.* No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) *Professional requirements*—(i) *General rule.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market,

sell, dispense, provide customer support for, or distribute OTC hearing aids.

(ii) *Sale of OTC hearing aids is not an exemption.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(iii) *Representations may create professional obligations.* A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) *Private remedies.* This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) *Incorporation by reference.* ANSI/CTA–2051, ''Personal Sound Amplification Performance Criteria,'' dated January 2017 (ANSI/CTA–2051:2017), is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*. The material may be obtained from Consumer Technology Association (CTA), Technology & Standards Department, 1919 S Eads Street, Arlington, VA 22202; phone: 703–907–7600; fax: (703) 907–7693; email: *standards@ce.org*, website: *www.cta.tech*.

[87 FR 50748, Aug. 17, 2022]

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

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

Subpart E—Other Exemptions

Subparts F–G [Reserved]

Subpart H—Special Requirements for Specific Devices

AUTHORITY: 21 U.S.C. 321, 331–334, 351, 352, 360d, 360i, 360j, 371, 374.

SOURCE: 41 FR 6896, Feb. 13, 1976, unless otherwise noted.

Subpart A—General Labeling Provisions

§ 801.1 Medical devices; name and place of business of manufacturer, packer or distributor.

(a) The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for ''Company,'' ''Incorporated,'' etc., may