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sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this paragraph shall be made available upon request at all reasonable hours by any officer or employee of the Food and Drug Administration or by any other officer or employee acting on behalf of the Secretary of Health and Human Services and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he deems necessary, and otherwise to check the correctness of such inventories.

(f) In addition, those persons conducting tests in accordance with paragraph (d) of this section shall maintain the results thereof and a description of the test method and of the test apparatus for a period of 3 years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Secretary of Health and Human Services. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.

(g) For the purpose of this section, the term ''manufacturer'' includes an importer for resale. Such importer may have the tests required by paragraph (d) of this section conducted in the country of origin but must make the results thereof available, upon request, to the Food and Drug Administration, as soon as practicable.

(h) All lenses must be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.

(i) This statement of policy does not apply to contact lenses.

[41 FR 6896, Feb. 13, 1976, as amended at 44 FR 20678, Apr. 6, 1979; 47 FR 9397, Mar. 5, 1982; 65 FR 3586, Jan. 24, 2000; 65 FR 44436, July 18, 2000; 69 FR 18803, Apr. 9, 2004]

§ 801.415 Maximum acceptable level of ozone.

(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

(b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.

(c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25 °C (77 °F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in

which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.417 Chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

[43 FR 11318, Mar. 17, 1978]

§ 801.422 Prescription hearing aid labeling.

(a) *Scope.* This section specifies the labeling requirements for prescription hearing aids. Any hearing aid that does not satisfy the requirements of § 800.30 of this chapter shall be a prescription device. 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. This section does not apply to group auditory trainers.

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

Dispenser. A dispenser is any person, as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person.

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.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an over-the-counter (OTC) hearing aid as defined in § 800.30 of this chapter or a hearing aid that does not satisfy the requirements in § 800.30 of this chapter.

Rebuilt hearing aid. A prescription 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, and adequately reprocessed the device for the next user.

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

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.* A prescription hearing aid shall bear all of the following labeling:

(1) *Outside package labeling.* The outside package of a prescription 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) *Warning against use in people younger than 18 without prior medical evaluation.*