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Devices and Radiological Health
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Resistant Lenses:

Questions & Answers

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

HHS Publication FDA 87-4002

IMPACT RESISTANT LENSES

QUESTIONS AND ANSWERS

Project Officers

Walter M. Snesko and John F. Stigi
Office of Training and Assistance

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

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Eyeglasses and sunglasses are medical devices. As such, they are subject to medical device regulations under the Food, Drug, and Cosmetic Act. To reduce the number of eye injuries, eyeglasses and sunglasses must be fitted with impact-resistant lenses. Glass lenses, plastic lenses, or laminated glass lenses can be made impact resistant by any method. However, all lenses must be capable of withstanding the impact test described under 21 CFR Part 801.410(d)(2). This booklet answers questions on such topics as the lens testing apparatus, records maintenance, and exemptions to testing.

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INTRODUCTION

The Food and Drug Administration (FDA), the leading consumer protection agency in the United States, began to regulate eyeglasses in the early 1970's.

In 1984, 120 million persons in the U.S. wore eyeglasses and 19 million lenses were imported, constituting a $7.5 billion industry in the United States.

Eyeglasses and sunglasses are medical devices. As such, they are subject to medical device regulations under the Food, Drug, and Cosmetic Act. Other forms of eyewear such as safety glasses and sports glasses -- including swimmers' racing goggles, ski goggles, and racquetball glasses -- are not regulated as medical devices unless they have prescription lenses, and thus are not subject to the medical device regulations.

To reduce the number of eye injuries, eyeglasses and sunglasses must be fitted with impact-resistant lenses. Consumers should understand that the regulation requires a minimum level of impact resistance but does not require that the lens act as an unbreakable shield. Glass lenses, plastic lenses, or laminated glass lenses can be made impact resistant by any method. However, all lenses must be capable of withstanding the impact test described under 21 CFR Part 801.410(d)(2) (see Appendix D for the complete ruling, hereafter referred to as "the regulation"). The number of lenses actually tested for impact resistance within each batch or lot varies depending on material and type of lens [21 CFR Part 801.410(c)(3)]: all glass lenses for prescription use must be tested, but statistical sampling is allowable for over-the-counter glass lenses, glass laminate and plastic lenses, and also for prescription glass laminate and plastic lenses. Certain lenses which are prescribed infrequently for specific, uncommon visual needs have physical designs that render them unsuitable for impact testing. These lenses [see 21 CFR 801.410(c)(3) for specific types] must be rendered impact resistant but need not be tested. Statistically accurate samples of plastic lenses (prescription or over the counter (OTC)) and glass OTC lenses must be

ested for impact resistance. Because not all lenses are ested, it is possible that some lenses are not impact esistant, although most will be.

Consumers, manufacturers, and sellers should remember iat the strength of any lens is related to the condition of its rface. All lenses lose their impact strength in direct oportion to the breakdown of the polished surfaces. The eater the number and depth of any scratches, the weaker e lens becomes. For consumers, there is an inherent zard in continuing to wear scratched lenses because their ipact strength is reduced. Spectacle wearers also should be are that streetwear or dress plastic lenses are not neces-rily impact resistant simply because they are manufac-red of a plastic material. Although plastic lenses must ss the impact test, they are not necessarily the same as ifety glasses" for industrial use.

Since the first edition of this booklet was published in ne 1972, considerable changes have occurred in Federal gulation of impact-resistant lenses. This third edition plains the changes and continues to answer questions that ustry and consumers most frequently ask FDA about pact-resistant lenses.

Factors having significant influence on current require-nts of the regulation are as follows:

- the Medical Device Amendments of May 28, 1976, which established responsibility for enforcement and administration by the Center for Devices and Radiological Health (CDRH) within FDA.
- experience by FDA in applying the regulation to eyeglass and sunglass lenses.
- technological advancements in eyeglass lenses.
- changes in the marketplace for eyeglasses.
- the amendment of April 6, 1979, (44 FR 20676) to the regulation, which (1) allowed lenses to be tested for impact resistance by any test equivalent or superior to the drop-ball (referee) test, and (2) described specific prescription lenses that must be impact resistant, but need not be tested for impact resistance.

For more information on this topic, contact your local FDA district office (see Appendix A) or CDRH at either of the following addresses:

Food and Drug Administration
Division of Compliance Operations
8757 Georgia Avenue
Silver Spring, MD 20910

Division of Small Manufacturers Assistance
5600 Fishers Lane (HFZ-220)
Rockville, MD 20857
Phone (800) 638-2041

TESTING APPARATUS AND PROCEDURES

1. Q. What is the "Referee" or "Drop Ball" test and how is it done?

   A. The test used to determine impact resistance, and which is described in the regulation, is commonly called the "drop ball test." The term "referee test" refers to the use of this test in determining compliance with a regulation.

   The exact procedure for the impact test is given in 29 CFR 801.410(d)(2) (see Appendix C). In brief, though, a 5/8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball must strike within a 5/8-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this regulation, a lens will be considered to have fractured if it cracks through its entire thickness and across a complete diameter into two or more separate pieces, or if any lens material visible to the naked eye becomes detached from the ocular surface (i.e., the surface of the lens that is closest to the eye when the lens is in actual use).

2. Q. What criteria does FDA use to determine whether a fractured lens passes the test?

   A. If the crack or fracture in any lens continues from the outside (objective) surface through to the ocular surface, the crack is considered to be through the lens's entire thickness and the lens has failed the test. However, if a laminated lens has a crack only through to the lamina, not disturbing the other side of the lens, then the crack is not considered to be through the thickness and the lens has passed the test.

   A lens is not considered impact resistant if it cracks during the test and each piece is approximately 50 percent of the lens (i.e., across the diameter). However, if, for example, only 1/4 of the lens is separated from the remaining lens (not across the diameter), the lens *may* be considered impact resistant. Such determinations are subjective, and acceptability of the lens may depend on whether the sample being tested has a high failure rate. For example, if the lot being tested was not well within Acceptable Quality Level (AQL) of 6.5, general inspection level II in MIL STD 105D, and the decison to pass or fail the lot depended on this lens, the inspector should be prudent and consider the lens unacceptable. Likewise, a lens is not considered impact resistant if its ocular surface chips during the test. In use, this small segmented piece would represent a potential hazard to the eye.

3. Q. Must the apparatus used in the referee test have a tube to guide the steel ball as it falls toward the lens?

   A. No. The regulation provides that a tube may be used, but is not necessary. If used, however, the tube must not interfere with the free fall of the ball.

4. Q. May a referee apparatus, which has a base and rigidly attached fixtures that weigh less than 27 pounds, be modified to meet the weight specification?

   A. Yes. A heavier base plate may be used or a modification made, such as attaching the base plate to a workbench or table in such a way that the bench or table is considered to be an integral part of the support system or of the apparatus itself. FDA requires that the apparatus used to test the lenses have a solid support system. FDA will use test fixtures weighing more than 27 pounds.

5. Q. Does FDA require a neoprene gasket on testing apparatus requiring support tubes?

   A. Yes.

6. Q. May the manufacturer secure the lens in the testing apparatus to prevent lens movement or repeated impact with the ball following the first impact with the ball?

   A. The regulation contains no provisions for securing the lens. FDA does not intend to secure the lens during testing. Nevertheless, measures to protect the lens from damage during testing are permitted, as long as these measures do not interfere with the validity of the test results. (See Appendix C.)

7. Q. How may manufacturers test laminated lenses for impact resistance?

   A. Laminated eyeglasses or sunglasses may be drop ball tested individually or on the same statistical basis as plastic lenses unless they are of a type, as specified under 21 CFR 801.410(c)(3), unsuitable for impact testing.

8. Q. Must manufacturers test plastic lenses in a variety of thicknesses?

   A. Manufacturers must test plastic lenses on a batch-sampling statistical basis. The regulation states that the lenses tested "shall be representative of the finished forms ... of minimal lens thickness ...." (see Appendix C). In practice, this means that manufacturers who sell partially-ground lens blanks to optical laboratories or other reprocessors must (1) tell these customers the degree of thickness at which the lenses were tested and (2) caution them to test each lens that is further processed to a thickness less than this minimal level.

9. Q. May the manufacturer use tests other than the referee test to demonstrate impact resistance?

   A. An alternate method of testing the impact resistance of lenses may be used if the manufacturer can prove that the alternate method is equal or superior to the referee test. The FDA need not preapprove any alternate testing method.

10. Q. If a lens breaks during an FDA test, is the manufacturer in violation of the regulation?

    A. Not necessarily. Each situation will be reviewed and violations determined by the conditions surrounding the case and by the testing status of the lens (i.e., whether the lens was individually tested or was part of a batch sampled on a statistical basis).

WHO MUST TEST & WHEN

11. Q. Who should perform the test for impact resistance?

    A. The manufacturer, as defined in the answer to question 12, is responsible for performing the test for impact resistance.

12. Q. In terms of the regulation, who is the manufacturer?

    A. The manufacturer is the person who puts the lens in the form ready for its intended use or who alters the physical or chemical characteristics of the lens by such acts as grinding, heat treating, beveling, or cutting. For the purpose of this regulation the term "manufacturer" includes a company that imports eyeglasses for resale.

13. Q. At what stage of fabrication (manufacture) must impact-resistant lenses be tested?

    A. The lenses must be tested when fabrication and treatment are complete and the lenses are ready for insertion into the eyeglass or the sunglass frames.

The exception is that plastic lenses may be tested in the "uncut-finished" stage (i.e., when both surfaces are formed to prescription curvatures and thickness, but edges of the lenses are not yet cut to frame size and shape).

14. Q. Does the regulation apply to lenses manufactured abroad for import into this country?

A. Yes. The regulation applies to all lenses in interstate commerce, regardless of their origin.

15. Q. May an optical wholesaler or processing laboratory supply non-impact-resistant lenses to a retailer who, in turn, wants to render them impact resistant?

A. Yes.

16. Q. What is the interpretation of "finished lens" and "finished form," as used in the regulation? (See Appendix D.)

A. A "finished lens" is in "finished form" when all edging operations have been completed prior to the lens being mounted into a frame and delivered to the patient. At this point, a monolithic (nonlaminated) glass lens is ready to be treated for impact resistance and tested.

17. Q. If retailers put untested plano (noncorrective) lenses in frames such as those used with customized sunglasses, must they render the plano lenses impact resistant and test them?

A. Yes. However, mass-produced plano lenses for use in sunglasses need only be tested on a statistically significant, batch-sampling basis.

18. Q. May a glass lens, after it has been chemically or thermally treated for impact resistance, be processed further in any way?

A. Lenses that are treated for impact resistance by induced surface compression may be re-edged or modified for power. However, the beneficial effects of surface compression may be substantially reduced. Such lenses must be retreated and tested before they are dispensed to the patient.

19. Q. Does FDA stipulate one method that must be used in rendering eyeglass lenses impact resistant?

A. No. Any proven method may be used, provided that the lenses pass the referee test or an equivalent test.

EXEMPTIONS

20. Q. What special prescription eyeglass lenses are exempt from the impact test?

A. As designated in the regulation, the following special lenses are exempt from statistical sampling and 100 percent impact testing: prism segment multifocals, slab-off prisms, lenticular cataracts, iseikonics, depressed segment one-piece multifocals, bioconcaves, myodiscs and minus lenticulars, and custom laminate and cemented assemblies. In addition, raised multifocal lenses need not be tested beyond initial design testing. All of these types of lenses are required to be made of impact-resistant materials or to be treated for impact resistance.

21. Q. Are toy sunglasses subject to the provisions of the regulation?

A. Yes. Toy sunglasses are subject to the provisions of the Federal Food, Drug, and Cosmetic Act, and if intended for wear by children, they also are subject to the provisions of the Federal Hazardous Substances Act, as amended by the Child Protection and Toy Safety Act of 1969.

SAMPLING PLANS

22. Q. How does the regulation define the word "batch" as as used in the phrase "statistically significant batch testing?"

    A. The regulation allows each manufacturer to define what constitutes a batch for their operation, as long as a "batch" is a recognizable or identifiable entity, and appropriate records are maintained.

23. Q. Does FDA require manufacturers to use a specific sampling plan when performing "statistically significant" sampling of lenses?

    A. FDA does not require the use of a specific sampling plan, however, the plan chosen must be statistically significant. FDA has accepted the use of MIL-STD 105D, April 1963, "Sampling Procedures and Tables for Inspection by Attributes," Acceptable Quality Level of 6.5, General Inspection Level II. Another acceptable plan, used by many foreign manufacturers, is the LTPD 15 percent sampling plan. The sample size is smaller than MIL-STD 105D with a correspondingly smaller rejection number. Other sampling plans are acceptable if shown to be statistically significant.

RECORDS

24. Q. What are the recordkeeping requirements on partially finished lenses furnished by one manufacturer for completion by another?

    A. Records must be kept to show how lenses were rendered impact-resistant, when and how they were tested for impact resistance, and by whom in the processing chain these actions were accomplished.

25. Q. What records must retailers maintain?

    A. If the retailer is also the manufacturer (see question 12), then the retailer is responsible for assuring the impact resistance of any lenses processed. The recordkeeping requirements of the manufacturer apply to the retailer in this case.

    In addition, the regulation requires retailers of prescription lenses to keep for 3 years records of the names and addresses of persons buying impact-resistant eyeglasses and sunglasses. The regulation does not require retailers to keep records of the names and addresses of people buying nonprescription glasses and sunglasses.

26. Q. Does the regulation call for coding of invoices, shipping documents, and containers pertaining to sale and distribution of impact-resistant lenses?

    A. No.

DISPENSING UNTESTED LENSES

27. Q. Under what circumstances may retailers dispense lenses that are not impact-resistant?

    A. Lenses that are not impact resistant may be dispensed when a physician or optometrist determines that impact-resistant lenses will not fulfill the visual requirements of a particular patient. The physician or optometrist directs this in writing and gives written notification to the patient.

28. Q. Can a retailer supply a non-impact-resistant lens if a patient requests it or if the patient/customer agrees to assume all responsibility?

    A. No. Non-impact-resistant lenses may be provided only when the physician or optometrist determines that impact-resistant lenses will not fulfill the visual requirements of the patient. (See question 27.) In such cases the physician or optometrist must give

notice in writing to the patient, explaining that the patient is receiving a lens that is not impact resistant.

29. Q. May a physician or optometrist prescribe non-impact-resistant lenses for a patient for purely cosmetic reasons?

    A. No. If medical problems are related to cosmetic considerations, however, the physician or optometrist may invoke special exemption provisions of the regulation based on professional judgment. For example, if the patient's prescription cannot be filled by impact-resistant lenses because the physician or optometrist knows from previous experience that the weight of the heavy lenses may cause headaches, undue pressure on the bridge of the nose or ears, pressure sores, etc., the physician or optometrist may find that the visual requirements of the patient cannot be met by use of impact-resistant lenses.

30. Q. Under rare circumstances - such as an emergency in which a surgeon's eyeglasses break just before a scheduled surgery, and the broken lenses must be replaced immediately - may a retailer provide non-impact-resistant lenses?

    A. If all else fails, and the situation is indeed critical, the surgeon may be provided with non-impact-resistant lenses on a temporary basis only and with the knowledge and consent of all involved.

FRAMES AND DESIGNS

31. Q. Does FDA restrict the properties or design of impact-resistant lenses?

    A. The regulation requires only that lenses be made impact resistant and be impact tested. No other FDA regulations are currently in effect concerning other properties or design of impact-resistant lenses.

32. Q. Must rimless eyewear pass the referee test?

    A. Yes. Rimless eyewear must conform to the regulation and pass the referee test or its equivalent.

33. Q. Does FDA regulate spectacle frames?

    A. Yes. Spectacle frames are regulated as medical devices. Spectacle frames are proposed for classification under 886.5270 as Class II medical devices.

OTHER LENS TYPES

34. Q. Are safety lenses the same as impact-resistant lenses?

    A. No. Safety lenses ordinarily are used in the industrial setting and are highly impact resistant, whereas impact-resistant lenses are used in street wear or dress wear eyeglasses.

35. Q. Does the regulation apply to industrial safety lenses?

    A. It is not necessary to apply the FDA impact requirement to industrial safety lenses, because these lenses are required by industrial standards to withstand impact stress nearly three times greater than the degree of impact resistance required by FDA. Industrial lenses are regulated by the Occupational Safety and Health Administration of the Department of Labor.

36. Q. Are impact-resistant lenses shatterproof or non-breakable?

    A. Neither. They are impact resistant, in that they are capable of passing the referee test (drop ball test) as described in the regulation. However, impact-resistant lenses may break or shatter under certain conditions. Impact-resistant lenses should not be worn in areas or situations requiring industrial safety lenses.

37. Q. Are the various forms of goggles or face masks, such as used in skiing, swimming, snorkeling, etc., subject to the provisions of this regulation?

A. No. The regulation applies only to eyeglasses and sunglasses; that is, to those products that are considered medical devices for street wear or dress use.

38. Q. Must demonstration lenses that are used in eyeglasses and sunglasses for display purposes be impact resistant?

A. Demonstration lenses are not required to be impact resistant. However, precautions must be taken to assure that these display units are not ultimately sold to the consumer. Manufacturers of eyeglass or sunglass frames with demonstration lenses can use any of various options to ensure that these units are not used by the public. These options are listed below.

1. At least one lens in each pair of eyeglasses should have the word "demonstration" etched in its lower quadrant. The letters should be large enough to be easily seen with normal vision.
2. A visible line may be drawn through the center of the lens.
3. A notch can be removed from the lower quadrant of at least one lens in each pair of eyeglasses.
4. A hole can be drilled in each lens in the wearer's line of sight.

PREMARKET NOTIFICATION

39. Q. Because spectacle frames and nonprescription sunglasses are common products, must manufacturers submit a premarket notification 510(k), like other medical device manufacturers?

A. Yes, however spectacle frames and sunglass manufacturers should not make complex premarket notification 510(k) submissions. When submitting the premarket notification 510(k), specifically address the following areas:

For spectacle frames, discuss the material used in its manufacture. If it is plastic, has it been tested for flammability? What are its dermatological characteristics? How does the strength and resilience of the proposed material compare to that commonly used?

For sunglasses, discuss whether the product consists of absorbing, reflective, tinted, polarizing, or photosensitized lenses. If claims are made for reduction of UV transmission, how was the percentage of reduction determined? Especially for a new material, how does it respond to drop ball testing?

LIABILITY

40. Q. What is the personal liability, with regard to injury claims, of a physician, optometrist, optical retailer, or optical wholesaler under the regulation?

A. Personal liability should be discussed with an attorney or with professional guilds or associations and their counsels.

REFERENCES

1. American National Standards Institute. "Practice for Occupational and Educational Eye and Face Protection." ANSI Z87.1, New York (1979).

2. American National Standards Institute. "Recommendations for Prescription Ophthalmic Lenses." ANSI Z80.1, New York (1979).

3. American National Standards Institute. "Sunglasses and Fashion Eyewear." ANSI Z80.3, New York (1986).

4. American National Standards Institute. "Dress Frames." ANSI Z80.5, New York (1986).

5. U.S. Department of Defense. "Sampling Procedures and Tables for Inspection by Attributes." MIL-STD-105D. Washington, D.C. (1975).

6. Department of Health, Education, and Welfare. Question and Answer Pamphlet #1 on Impact-Resistant Lenses. HEW Publication (FDA) 72-4002 (1972).

American national standards can be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

Military standards can be obtained from the U.S. Naval Publications and Forms Center, 5801 Tabor Avenue, Philadelphia, PA, 19120.

APPENDIX A. FDA DISTRICT OFFICES

Food & Drug Admin.
1521 W. Pico Blvd.
Los Angeles, CA 90015-2486
Phone: (213) 688-3776

Food & Drug Admin.
50 United Nations Plaza
Federal Office Bldg, #526
San Francisco, CA 94102
Phone: (415) 556-0318

Food & Drug Admin.
500 U.S. Customhouse
721 19th St.
Denver, CO 80202
Phone: (303) 837-4915

Food & Drug Admin.
7200 Lake Ellenor Dr.
Suite 120
Orlando, FL 32809
Phone: (305) 855-0900

Food & Drug Admin.
1010 W. Peachtree St., N.W.
Atlanta, GA 30309
Phone: (404) 881-4266

Food & Drug Admin.
1222 Post Office Bldg.
433 W. Van Buren St.
Chicago, IL 60607
Phone: (312) 353-7379

Food & Drug Admin.
4298 Elysian Fields Ave.
New Orleans, LA 70122
Phone: (504) 589-2401

Food & Drug Admin.
585 Commercial St.
Boston, MA 02109
Phone: (617) 223-5066

Food & Drug Admin.
900 Madison Ave.
Baltimore, MD 21201
Phone: (301) 962-4012

Food & Drug Admin.
1560 E. Jefferson Ave.
Detroit, MI 48207
Phone: (313) 226-6260

Food & Drug Admin.
240 Hennepin Ave.
Minneapolis, MN 55401
Phone: (612) 787-3904

Food & Drug Admin.
St. Louis Station
808 N. Collins St.
St. Louis, MO 63102
Phone: (314) 425-4137

Food & Drug Admin.
1009 Cherry St.
Kansas City, MO 64106
Phone: (816) 374-5521

Food & Drug Admin.
20 Evergreen Pl.
East Orange, NJ 07018
Phone: (201) 645-3023

Food & Drug Admin.
850 Third Ave.
Brooklyn, NY 11232
Phone: (718) 965-5301

Food & Drug Admin.
599 Delaware Ave.
Buffalo, NY 14202
Phone: (716) 846-4478

Food & Drug Admin.
1141 Central Pkwy.
Cincinnati, OH 45202
Phone: (513) 684-3504

Food & Drug Admin.
900 U.S. Customhouse
2nd & Chestnut St.
Philadelphia, PA 19106
Phone: (215) 597-3040

Food & Drug Admin.
Fernandez Juncos Ave.,
Stop 8½
Puerto de Tierra
San Juan, PR 00905
Phone: (809) 753-4245

Food & Drug Admin.
297 Plus Park Blvd.
Nashville, TN 37217
Phone: (615) 251-5851

Food & Drug Admin.
1032 Bryan St.
Dallas, TX 75204
Phone: (214) 767-0317

Food & Drug Admin.
Houston Station
1440 North Loop, Suite 250
Houston, TX 77009
Phone: (713) 229-3530

Food & Drug Admin.
909 First Ave.
Room 5003
Seattle, WA 98174
Phone: (206) 442-5304

APPENDIX B. VOLUNTARY STANDARDS

The American National Standards Institute (ANSI) standard Z80.1, "Recommendations for Prescription Ophthalmic Lenses," permits the use of a plastic film on top of the lens during the impact test, as follows:

> "To avoid surface damage from the impact of the ball, the lens may be inserted in a polyethylene bag or covered with a polyethylene sheet before testing. The thickness of polyethylene covering the lens shall not exceed 0.076 mm (0.003 in.), and shall conform to the requirements for polyethylene sheeting, Type II, given in ANSI Specification for Polyethylene Film and Sheeting, ANSI/ASTM D2103, 1971, or the latest revision thereof. The protective sheet shall be in contact with the lens surface in the test area before the ball is dropped."

FDA agrees to accept this practice when a method of 100 percent testing of finished lenses is used, although FDA realizes that the impact energy of the falling ball, as transmitted to the lens, may be reduced by more than 10 percent. FDA still affirms, however, that in any case of dispute, the referee test as described in 21 CFR 801.410 will prevail. Also, for any new developments in the materials of lenses, the referee test shall be used in verifying conformance of the new material to these specifications.

Restriction: When the impact resistance of the lenses is verified by a statistical sampling plan, FDA insists that the referee test, or its equivalent or superior, be used without the plastic film.

APPENDIC C. FEDERAL REGULATION ON IMPACT-RESISTANT LENSES

TITLE 21 - FOOD AND DRUG ADMINISTRATION PART 801 - LABELING

Subpart H - Special Requirements for Specific Devices

§801.410 Use of impact-resistant lenses in eyeglasses and sunglasses

(a) Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

(b) The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses.

(c)(1) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

(2) The physician or optometrist shall have the option of ordering glass lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d)(2) of this section.

(3) Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test described in paragraph (d)(2) of this section. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one-piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses (i.e., lenses other than those described in the three preceding sentences of this paragraph (c)(3)), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form.

(d)(1) For the purpose of this regulation, the impact test described in paragraph (d)(2) of this section shall be the "referee test," defined as "one which will be utilized to determine compliance with a regulation." The referee test provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test described in paragraph (d)(2) of this section or any equal or superior test. Whatever test is used, the lenses shall be capable of

withstanding the impact test decribed in paragraph (d)(2) of this section if the Food and Drug Administration examines them for performance.

(2) In the impact test, a 5/8-inch steel ball weighing approximately 0.56 ounce is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a 5/8-inch diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately 4 inches of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube (1-inch inside diameter, 1¼-inch outside diameter and approximately 1-inch high) affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall not be less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less the 1¼ inches may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a $\frac{1}{8}$- by $\frac{1}{8}$-inch neoprene gasket having a hardness of 40±5, as determined by ASTM Method D 1415;[1] a minimum tensile strength of 1,200 pounds, as determined by ASTM Method D 412;[1] and a minimum ultimate elongation of 400 percent, as determined by ASTM Method D 412 (ASTM Methods D 412 and D 1415 are incorporated by reference)The diameter or contour of the lens support may be modified as necessary so that the $\frac{1}{8}$- by $\frac{1}{8}$-inch neoprene gasket supports the lens at its periphery.

[1]Copies may be obtained from: American Society for Testing Materials (ASTM), 1916 Race St., Philadelphia, PA 19103

(e) Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of 3 years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and 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.

Note: The text of this regulation has been retyped and is included for information purposes only. Persons wishing to cite the regulation for legal purposes should consult the actual text contained in the Code of Federal Regulations

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"_____(Name of manufacturer or seller) hereby guarantees that the articles listed herein are impact-resistant within the meaning of 21 CFR 801.410 and have been tested pursuant to that section. Impact-resistant lenses are not unbreakable or shatterproof. Records of testing will be maintained for a period of three (3) years from the date of shipment, and copies will be forwarded to FDA upon request."

(Signature and post office address of manufacturer or seller)