Guidance for Industry and FDA Staff

Impact-Resistant Lenses: Questions and Answers

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Small Manufacturers, International and Consumer Assistance
Office of Communication, Education, and Radiation Programs

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. When submitting comments, please refer to Docket No. FDA-2007-D-0367. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

Impact-Resistant Lenses: Questions and Answers

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Eyeglasses and sunglasses (eyewear) that are intended to affect the structure or function of the body or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)). These devices are subject to applicable device regulations under Title 21, Code of Federal Regulations. Impact-resistant lenses reduce the number of eye injuries from eyeglasses and sunglasses. Glass lenses, plastic lenses, or laminated glass lenses can be made impact resistant by any method. However, lenses generally must be capable of withstanding the impact test described in 21 CFR 801.410. This guidance answers questions for manufacturers, importers, and testing laboratories on such topics as test procedures, lens testing apparatus, record maintenance, and exemptions to testing.

This guidance is a revision of “Impact-Resistant Lenses: Questions and Answers (FDA 87-4002),” issued September 1987. This guidance updates answers to questions that industry and consumers frequently ask FDA about impact-resistant lenses and FDA regulation of eyewear. The revision reflects the exemption of sunglasses from the Premarket Notification (510(k)) requirement effective February 19, 1998 (21 CFR 886.5850(b)). The revised document also includes a more detailed discussion about lens blanks, semi-finished, finished, and plano lenses, as well as import procedures. We use the terms "eyeglasses" and "spectacles" interchangeably in this document.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Overview

Eyewear products regulated by FDA are commonplace in the daily lives of the vast majority of the general public. FDA believes that impact-resistant lenses are an essential component of the safe design of these devices.

The use of impact-resistant lenses in eyeglasses and sunglasses is addressed in 21 CFR 801.410. Except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs the use of other lenses in writing, and gives written notification to the patient, eyeglasses and sunglasses must be fitted with impact-resistant lenses (21 CFR 801.410(c)(1)). Glass lenses, plastic lenses, or laminated glass lenses can be made impact resistant by any method. However, in accordance with 21 CFR 801.410(c)(2), all such lenses must be capable of withstanding the impact test described in 21 CFR 801.410(d)(2). Although lenses must be impact resistant, it does not make the lenses shatterproof.

The number of lenses actually tested for impact resistance within each batch or lot varies depending on material and type of lens (21 CFR 801.410(c)(3)). You must perform impact testing on each glass lens for prescription use (21 CFR 801.410(c)(3)). However, you may test a statistically significant sample of lenses from each production batch for testing of over-the-counter (OTC) glass lenses, glass laminate (prescription or OTC), and plastic lenses (prescription or OTC) for impact resistance. Certain lenses, which are prescribed infrequently for specific, uncommon visual needs, have physical designs that make them unsuitable for impact testing. These lenses (see 21 CFR 801.410(c)(3) for specific types) should be rendered impact resistant but need not be tested.

Consumers, manufacturers, and sellers should remember that the strength of any lens is related to the condition of its surface and edge. All lenses lose their impact strength in direct proportion to the breakdown of the polished and edged surfaces. The greater the number and depth of scratches or the poorer the edge finish, the weaker the lens becomes. For consumers, there is an inherent hazard in continuing to wear scratched lenses because their impact strength is reduced. Spectacle wearers also should be aware that plastic lenses are not necessarily impact resistant simply because they are manufactured of a plastic material.

FDA does not regulate other forms of eyewear, such as safety glasses and sports glasses (including swimmers' racing goggles, ski goggles, and racquetball eye guards), as devices unless they have ultraviolet (UV) prescription lenses.

We recommend you also refer to “Guidance Document for Nonprescription Sunglasses” at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073951.htm.

For more information on this topic, you may contact the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) by phone at 1-800-638-2041, by fax at 301-847-8149, by e-mail at dsmica@fda.hhs.gov, or write to the following address:

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Center for Devices and Radiological Health
Office of Communication, Education and Radiation Programs
Division of Small Manufacturers, International, and Consumer Assistance
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Prescription and Non-Prescription Glass Lenses

1. **Q.** What are the impact testing requirements for prescription (Rx) glass lenses?

   A. The manufacturer must test each finished Rx glass lens individually for impact resistance (21 CFR 801.410(c)(3)). The lens must be capable of withstanding the impact test provided in 21 CFR 801.410(d)(2) as described later in this document under "Testing Apparatus and Procedure." You should perform testing after the lens has been edged (cut to the shape of the frame) but before the lens is put into the frame.

2. **Q.** What are the impact testing requirements for non-prescription (over-the-counter) glass lenses, e.g., magnifying spectacles and nonprescription sunglasses? Magnifying spectacles are intended to be worn by a patient who has impaired vision to enlarge images. See 21 CFR 886.5840. Nonprescription sunglasses are intended to be worn to protect the eyes from bright sunlight but not to provide refractive corrections. See 21 CFR 886.5850.

   A. Under 21 CFR 801.410(c)(3), you must test a statistically significant sample of over-the-counter glass lenses from each production batch. The sample must be representative of the finished forms as worn by the wearer, including forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. You must test all nonprescription lenses in either uncut-finished or finished form. 21 CFR 801.410(c)(3). If you choose to test the finished form, you should perform testing, on a sample, after the lens has been edged (cut to the shape of the frame) but before being put into the frame.

3. **Q.** Can a glass lens that is chemically or thermally treated for impact resistance be further processed?

   A. You may re-edge or modify the power (resurface) of lenses that have been chemically or thermally treated for impact resistance. However, this may significantly reduce the resistance to impact. You should re-treat and retest the lenses before delivering them to the end customer.

Prescription and Non-Prescription Plastic Lenses

4. **Q.** What are the impact testing requirements for prescription (Rx) and non-prescription plastic lenses?

   A. Under 21 CFR 801.410(c)(3), you must test a statistically significant sample of prescription or non-prescription plastic lenses from each production batch. The sample must be representative of the finished forms as worn by the wearer, including forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. You must test plastic lenses in either uncut-finished or finished form.

21 CFR 801.410(c)(3). If you choose to test the finished form, you should perform testing on a sample after the lens has been edged (cut to the shape of the frame) but before being put into the frame.

Finished Lenses

5. Q. What is meant by a “uncut finished” or “finished form” in 21 CFR 801.410(c)(3)?

A. “Uncut-finished” means a lens with both surfaces optically shaped but not yet edged. FDA considers a lens to be a "finished device" or in "finished form" when both surface and edging operations have been completed, and coating and treatment for impact resistance has been applied, if appropriate.

Lens Blanks (Semi-Finished Lens)

6. Q. What is a "semi-finished” lens?

A. FDA considers a "semi-finished” lens to be a lens with only one surface (usually front surface) shaped or molded to a specific curve.

7. Q. Is the manufacturer of semi-finished lens required to perform the impact testing?

A. No. A semi-finished lens needs further processing that may weaken the lens. You must test the uncut-finished or, the finished lens if it is a glass lens for prescription use. 21 CFR801.410(c)(3)

Plano (Non-Corrective) Lens

8 Q. What is a "plano" lens?

A. A plano lens is a lens with no corrective power and essentially no refracting ability. For example, when one eye needs refractive correction and the other eye does not, you may use the plano lens for the eye that requires no correction.

9. Q. Does impact testing apply to retailers that put plano lenses in sunglass frames or that put lenses into an eyeglass frame in which one lens is plano and the other lens is corrective?

A. Yes. Testing depends on lens material. Retailers that process lenses (grind and shape) must render the plano lenses impact resistant. Finished glass lenses should be tested regardless of optical power while plastic lenses can be statistically sampled or certified to the design testing specifications.

Sunglasses

10. Q. Does impact testing apply to finished non-prescription sunglass lenses, i.e., sunglass lenses that need only to be inserted into a frame?

A. Yes. Under 21 CFR 801.410(c)(3), you must test a statistically significant sample of sunglass lenses from each production batch. The sample must be representative of the finished forms, including forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. You must test all lenses in uncut-finished or finished form. 21 CFR 801.410(c)(3). If you choose to test the finished form, you should perform testing on a sample after the lens has been edged (cut to the shape of the frame) but before being put into the frame.

11. Q. Are clip-on sunglass lenses subject to impact testing?

A. Yes (21 CFR 801.410 (c)(3)). However, FDA intends to exercise its enforcement discretion regarding impact testing based on the following factors:

1. Whether the clip-ons cannot be worn alone, but can only be worn with lenses that are impact resistant.
2. Whether the clip-ons are designed so that they may be worn only on the outside (side distal from the eye) of the prescription lenses.
3. Whether the clip-ons are the same size or smaller than the prescription lenses upon which they are intended to be worn.

Novelty and Children's "Toy" Sunglasses

12. Q. Is novelty eyewear subject to the impact testing regulations?

A. FDA strongly recommends that you conduct impact testing of any glass or plastic lenses used in novelty eyewear to help ensure the safe design of these products.

In general, FDA does not require impact testing of novelty eyewear if:

(1) the item is a novelty item, which is not intended to provide children (or other users) with corrective power or protection from bright sunlight; and
(2) a warning label stating that the item is not to be worn outside as sunglasses to protect the eyes against strong sunlight is placed on eyewear that has dark-colored lenses.

However, all novelty eyewear may be subject to regulation by the Consumer Product Safety Commission (CPSC) under the provisions of the Federal Hazardous Substances

Act (FHSA)[1]. The regulations are found in 16 CFR 1500, Hazardous Substances and Articles; Administration and Enforcement Regulations, and 16 CFR 1501, Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts.

13. Q. Are children's sunglasses subject to the impact testing regulations?

A. Children's sunglasses, intended for use by a child in the protection of his or her eyes from bright sunlight, are subject to all of the applicable requirements, including impact testing. Children's sunglasses that are devices within the meaning of section 201(h) of the act are also subject to the CPSC regulations under 16 CFR parts 1500 and 1501 discussed previously in response to Question #12.

If they meet the criteria outlined in response to Question #12, children's sunglasses may be novelty glasses that are not regulated as medical devices by FDA. However, they, too, may still be subject to the hazardous substance regulations of the CPSC (see 16 CFR Parts 1500 and 1501).

14. Q. What are the testing requirements for children's "toy" sunglasses?

A. If children's toy sunglasses are intended to provide protection from bright sunlight, such as sunglasses sold or given away in fast food restaurants as promotional items, they must meet the impact test (21 CFR 801.410).

Other Lens Types

15. Q. What is the difference between "safety lenses" and "impact-resistant lenses"?

A. Safety lenses have more stringent impact-resistant requirements and are used in an industrial setting. Impact-resistant lenses are used in (1) eyeglasses, (2) sunglasses, and (3) noncorrective fashion eyewear.

16. Q. What regulations apply to industrial safety lenses?

[1] The Federal Hazardous Substances Act regulations in 16 CFR 1500.3(a)(1), defines "Act" as the Federal Hazardous Substances Act (Pub. L. 86-613, 74 Stat. 372-81 (15 U.S.C. 1261-74)), and amendments to such Act.

A. Both FDA and the Occupational Safety and Health Administration (OSHA) regulate industrial prescription safety lenses. Under 21 CFR 801.410, these lenses must be impact resistant. If the industrial prescription safety lenses meet OSHA requirements under 29 CFR 1910.133(b), then FDA believes it is appropriate to exercise its enforcement discretion with respect to the need for further impact testing under 21 CFR 801.410(d) for such lenses. Under 29 CFR 1910.133(b), protective eye devices must comply with ANSI Z87.1–1989, "American National Standard Practice for Occupational and Educational Eye and Face Protection," (if purchased after July 5, 1994) and ANSI "USA Standard for Occupational and Educational Eye and Face Protection," Z87.1–1968 (if purchased before July 5, 1994). FDA considers ANSI Z87.1 to meet or exceed impact testing under 21 CFR 801.410.

OSHA, not FDA, regulates non-prescription safety lenses. FDA impact test requirements do not apply to non-prescription safety lenses.

17. Q. What regulations apply to sports goggles, such as skiing, swimming, and snorkeling?

A. Sports goggles with prescription lenses are regulated as devices. Manufacturers must meet all applicable device regulations, including impact resistance (21 CFR 801.410), establishment registration (21 CFR Part 807), device listing (21 CFR Part 807), quality system regulation (21 CFR Part 820), and medical device reporting (21 CFR Part 803). Prescription sports goggles should also meet the appropriate safety standards for the sport.

Non-corrective sports goggles that do not make any sun protection claims are not regulated as devices. Therefore, no device regulations, such as registration or listing, apply.

18. Q. What regulations apply if sports goggles use the following claims: "Blocks UV," "Blocks Sunrays," or makes other sunglass claims?

A. FDA regulates goggles, including sports goggles and tanning bed goggles, that make such claims as sunglasses. Therefore, goggles making such claims must meet the same regulations as sunglasses, including impact resistance. 21 CFR 801.410.

19. Q. What regulations apply to demonstration lenses used in eyeglasses and sunglasses for retail display?

A. Demonstration lenses are typically not rendered impact resistant as they are not intended to be sold to consumers. You should take precautions to assure that display units containing demonstration lenses that are not impact-resistant are not sold to the consumer. Manufacturers of eyeglass or sunglass frames with demonstration lenses can use various options to ensure these units are not used by consumers. The options include the following:

1. You may have the word "demonstration" etched in the lower quadrant of at least one lens in each pair of eyeglasses. The letters should be large enough to be seen easily with normal vision.

2. You may draw a visible line through the center of the lens.
3. You may remove a notch from the lower quadrant of at least one lens in each pair of eyeglasses.
4. You may drill a hole in each lens in the wearer's line of sight.

Demonstration lenses that are devices within the meaning of section 201(h) of the act and that are offered for sale or distribution to consumers must undergo impact testing under 21 CFR 801.410.

Who Should Test and When

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

A. The manufacturer must perform the test for impact resistance (21 CFR 801.410(d)(1)). Manufacturer is defined under 21 CFR 820.3(o) and would include the person (or firm) who puts the lens in the form ready for its intended use or who alters the physical or chemical characteristics of the lens by grinding, heat treating, beveling, applying scratch resistant coating, applying anti-reflection coating, cutting, or other pertinent actions. Manufactures of all plastic lenses and non-prescription glass lenses may test at the uncut-finished or finished stage while glass prescription lenses must be tested at the finished stage. Retail laboratories that perform some or all of these processes are manufacturers. For the purpose of 21 CFR 801.410, the term "manufacturer" also includes a company that imports impact resistant lenses for eyeglasses, or who imports finished eyeglasses or sunglasses for resale. (21 CFR 801.410(g))

21. Q. When should lenses be tested for impact resistance?

A. You should test lenses when the manufacture and treatments described in Question # 20 are complete and the lenses are ready to insert into eyeglass or sunglass frames.

22. Q. Do the impact-resistant lenses regulations apply to lenses manufactured outside the U.S. for import into the U.S.?

A. Yes. 21 CFR 801.410 applies to all lenses in interstate commerce regardless of their origin.

23. Q. Should retail laboratories perform impact-resistant testing?

A. Yes. Because drilling holes, grinding surfacing, and applying coatings may weaken the lens, the retail laboratory should make the lens impact resistant and test the lens before delivery to the user.

24. Q. What is a "Certification Statement of Impact Resistance" and who issues it?

A. A "Certification Statement of Impact Resistance" is a written statement from the manufacturer guaranteeing that the lenses have been tested and are impact resistant. FDA may accept such a certification in lieu of test results, but a manufacturer must make the results available, upon request, to the FDA as soon as practicable. 21 CFR 801.410(g). Suggested wording can be found in Appendix C.

25. Q. Can a third-party laboratory test the lenses?

A. Yes. The third-party laboratory can conduct the impact test on behalf of the manufacturer. The manufacturer, not the third party laboratory, should render the lenses in finished form for testing. Although a third-party may conduct the testing, the manufacturer should issue the certification and be named in any certification issued to it by the third party.

Testing Apparatus and Procedure

26. Q. Does FDA prefer a particular method for making eyeglass lenses impact resistant?

A. No. FDA has no preference for a particular method. You may use any method, provided that the lenses pass the referee test or an equal or superior test. 21 CFR 801.410(d)(1).

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

A. The terms referee test, “drop ball” test, and impact test are similar. The test described in 21 CFR 801.410(d)(2) is commonly called the drop ball or impact test. We use the term "referee test" when we perform the test to determine compliance with the regulation. 21 CFR 801.410(d)(1).

The regulation at 21 CFR 801.410(d)(2) describes the exact procedure for the impact test (See Appendix A). The regulation states, “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….”

28. Q. What constitutes failure to pass the impact test? That is, when is the lens not impact resistant (fractured)?

A. A lens is fractured and not considered impact resistant if (21 CFR 801.410(d)(2)):

1. it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces; or

2. 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).

If a laminated lens has a crack only through to the lamina and does not disturb the other side of the lens, we do not consider the crack to be through the entire thickness and the lens passes the test.

29. Q. Does the apparatus that FDA uses in the referee test have a tube to guide the steel ball as it falls toward the lens?

A. Yes. The ball may be guided with a tube that does not restrict its fall while dropping. The bottom of the tube must end within approximately 4 inches of the lens (21 CFR 801.410(d)(2)). Although you may use a guide tube, it is not necessary.

30. Q. Can the firm modify its referee apparatus to meet the weight specification?

A. Yes. The total weight of the base plate and its rigidly attached fixtures cannot be less than 27 pounds (21 CFR 801.410(d)(2)). You may use a heavier base plate or make a modification, such as attaching the base plate to a work bench or table so that the bench or table is an integral part of the support system or the apparatus itself. The apparatus you use to test the lenses should have a solid support system. FDA will use test fixtures weighing more than 27 pounds.

31. Q. Should a neoprene gasket be securely bonded to the support tube?

A. Yes. The test must be conducted with the lens supported by a tube affixed to a rigid iron or steel base plate. 21 CFR 801.410(d)(2). The support tube must be 1-inch inside diameter, 1 1/4-inch outside diameter, and approximately 1-inch high and made of rigid acrylic plastic, steel, or other suitable substance. A neoprene gasket must be securely bonded on the top edge of the support tube. The neoprene gasket must be 1/8- by 1/8-inch in size and have a hardness of 40 +/-5, a minimum tensile strength of 1,200 pounds, and a minimum ultimate elongation of 400 percent (21 CFR 801.410(d)(2)). See Appendix B for a photograph of the test apparatus.

32. Q. Can a manufacturer secure the lens in the testing apparatus to prevent lens movement or repeated impact with the ball?

A. FDA does not secure the lens during FDA testing and the regulation contains no provisions for securing the lens. However, you may use measures to protect the lens from damage during testing, as long as these measures do not interfere with the validity of the test results.

33. Q. How can manufacturers of eyeglasses or sunglasses test laminated lenses for impact resistance?

A. You may "drop ball" test laminated eyeglasses or sunglasses individually or on the same statistical basis as plastic lenses, unless they are of a type unsuitable for impact testing, as specified under 21 CFR 801.410(c)(3). See Question # 43 for exempt lenses.

34. Q. Should manufacturers test plastic lenses in a variety of thicknesses?

A. Yes. Manufacturers should test plastic lenses using a statistically significant sampling of lenses from each production batch. The regulation at 21 CFR 801.410(c)(3) states, "All non-prescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form." In practice, this means that manufacturers who sell semi-finished lenses or lens blanks to optical laboratories or other processors should take the following steps: (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.

35. Q. Can the manufacturer use tests other than the referee test to demonstrate impact resistance?

A. Yes. The manufacturer must conduct tests of lenses using the impact test in 21 CFR 801.410(d)(2) (referee test) or any equal or superior test. 21 CFR 801.410(d)(1). The manufacturer should maintain appropriate records to demonstrate that the alternate method is equal or superior to the referee test. The FDA does not need to pre-approve an alternate testing method. FDA, however, will use the referee test when it is testing lenses.

Sampling Plans

36. Q. What constitutes a "batch"?

A. The regulation requires testing of all non-prescription lenses and plastic prescription lenses on a "statistically significant sampling of lenses from each production batch" (21 CFR 801.410(c)(3)). The regulation allows each manufacturer to define what constitutes a batch for its operation. A batch should be a recognizable or identifiable entity, and the manufacturer must maintain appropriate records of batch testing. 21 CFR 801.410(f). When feasible, a batch represents a product quantity, which is similar in nature, given process variation, and can also be quarantined if drop ball test results show the batch has failed. In certain circumstances, it may be impossible to define a batch based upon uniform characteristics. For manufacturers who produce a large variety of individually prescribed lenses, each with varying characteristics, a batch size may be defined as a day or a week of production. For these manufacturers, the testing sample should contain appropriate proportions of the combinations of the different lens materials and coating so that it is representative of the entire batch.

37. Q. What type of sampling methods may manufacturers use to obtain a "statistically significant" sample of lenses?

A. FDA does not limit manufacturers to any specific sampling plan; however, you should use a valid statistical sampling plan. FDA has recognized the standards below. You may use either of these standards or an equivalent standard.

ANSI/ASQC Z1.4/1993, Sampling Procedures and Tables for Inspection by Attributes
American National Standard Institute (ANSI)
http://www.ansi.org

American Society for Quality (formerly America Society for Quality Control (ASQC)
http://www.asq.org

ISO 2859-1/1999, Sampling Procedures for Inspection by Attributes -- Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection
International Organization for Standardization (ISO)
http://www.iso.ch

CDRH supplemental information for these standards is available at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm or directly at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=1595 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=1585 for the ISO or ANSI document, respectively.

You can find information on how to purchase these standards by contacting the standards organization.

FDA will also accept the use of Military Standard 105E (MIL-STD 105E), May 10, 1989, "Sampling Procedures and Tables for Inspection by Attributes" at an Acceptable Quality Level (AQL) of 6.5, General Inspection Level II.

38. Q. If an optical wholesale laboratory or retail laboratory has multiple locations that use the same procedures and equipment, can testing lenses from one location for impact testing cover all locations for compliance with the regulation?

A. No. There may be subtle process differences at different locations that can affect the impact resistance of a lens (e.g., wear on a diamond wheel used in surfacing, age of polish, age of coatings, experience of operators). You must test statistically significant samples of each batch of nonprescription lenses and each batch of plastic prescription lenses as well as each glass prescription lens individually. 21 CFR 801.410(d)).

39. Q. If finished lenses fail impact testing, even when processed in accordance with the original manufacturer's recommendations, should the wholesale laboratory or retail laboratory notify the original lens manufacturer?

A. Manufacturers should manufacture and process lenses in accordance with the Quality System regulation under 21 CFR 820. If repeated failures occur, the wholesale

laboratory or retail laboratory should evaluate its processes to assure its processes are in control. If repeated failures continue, the laboratory should notify the original lens manufacturer.

Records

40. Q. What are the recordkeeping requirements for those persons conducting impact resistant testing under 21 CFR 801.410(d)?

A. Such persons must maintain the results of the testing, a description of the test method, and of the test apparatus for 3 years. 21 CFR 801.410(f).

41. Q. What records are manufacturers required to maintain?

A. Manufacturers are required to maintain the records referenced previously (Question #40). In addition, the manufacturer must maintain copies of invoices(s), shipping documents, and records of sale or distribution of all impact-resistant lenses, including finished eyeglasses and sunglasses for three years (21 CFR 801.410(e)).

42. Q. What information is the retailer required to keep on individuals purchasing eyeglasses or sunglasses?

A. There are no requirements for the retailer to keep and maintain the names and addresses of individuals purchasing **nonprescription** eyeglasses and sunglasses at the retail level under 21 CFR 801.410. However, the retailer should consult state law to determine relevant state requirements for the sale of prescription lenses.

Exemptions

43. Q. What lenses are exempt from the impact test?

A. The following special lenses must be impact resistant but are exempt from testing: "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." (21 CFR 801.410(c)(3))

Importing Lenses, Eyeglasses, and Sunglasses

44. Q. What should be submitted to the FDA at the U.S. Port of Entry?

A. Nearly all commercial entries come to FDA through the U.S. Customs and Border Protection's Automated Broker Interface (ABI) system submitted by a customs brokerage firm (or filer). FDA processes these entries electronically in its Operational and Administrative System for Import Support (OASIS) system.
To streamline the entry process, we recommend that you use the affirmation of compliance code, IRC, for electronic entries or submit a "Certification Statement of Impact Resistance." (See Q #24). We provide suggested wording for a certification statement in Appendix C.

If the lenses are manufactured outside the U.S., the foreign manufacturer should test the lenses prior to exporting to the U.S. The foreign manufacturer should provide a certification of impact resistance with the shipment of finished lenses that requires no further processing, except for being inserted into a frame.

If you import semi-finished prescription or non-prescription lenses into the U.S., you should label the lenses, "Requires further processing, not a finished device." Semi-finished lenses require further processing. Under these circumstances, the U.S. finished device manufacturer is responsible for performing the impact testing.

In addition to the certification statement, FDA reviews information you provide to demonstrate that the device meets FDA requirements. This includes registration number, device listing number, and U.S. Agent information for prescription spectacle lenses (21 CFR 886.5844), magnifying spectacles (21 CFR 886.5840), and sunglasses (nonprescription) (21 CFR 886.5850). If you are submitting an electronic entry through the ABI system, you should provide this information in the affirmation of compliance. If you are not submitting an electronic entry through the ABI system, you should annotate this information on U.S. Customs and Border Protection's entry declaration form that is appropriate for the type of entry and provide a copy to the FDA district office at the port of entry.

45. Q. What are FDA's processes for inspection and/or sampling for testing of a shipment of lenses or sunglasses?

A. Ophthalmic devices are subject to inspection and/or sampling by the FDA as part of FDA's efforts to determine the device's compliance with the act. FDA does not inspect every import entry. FDA may request additional information or documentation, such as records of impact testing results, or request to examine the shipment. If FDA chooses to collect a sample, the District Office typically notifies the import broker (or filer), the owner or consignee, and importer of record (if different than owner or consignee) of its intent to sample.
FDA provides official notification of the entry reviewer's decision to sample by submitting a "Notice of FDA Action" sampling request.

Once FDA has been advised of the location and the availability of articles, the FDA personnel will visit the site to perform the examination and/or sample collection. FDA's examination of the entry and sample collection cannot proceed until the agency receives the "notification of availability." After collection of the sample, FDA typically provides

an additional "Notice of FDA Action" detailing the articles and amounts collected. If the article is found to be in compliance after examination, the filer, importer of record, consignee, and the U.S. Customs and Border Protection (CBP) are notified by "Notice of Release" that the article may be admitted as far as FDA is concerned.

46. Q. If FDA tests the shipment at the port of entry, how many lenses are tested?

A. FDA will test a statistically significant sample size in order to determine compliance with the FDA impact test regulation. The sample size will depend on the size of the shipment that FDA is testing.

47. Q. What does the FDA testing lab do with sunglasses/eyeglasses after being tested?

A. Samples that are damaged are no longer suitable for use and are not returned to the importer. If requests are made to a District Office for the return of any non-damaged samples, FDA tries to comply with the requests.

48. Q. What should I do if my shipment is refused admission?

A. FDA may issue a "Notice of Detention and Hearing" to refuse admission of a shipment if the device appears to be in violation of section 801(a) of the act (21 U.S.C. 381(a)). FDA issues the "Notice of Detention and Hearing" detention to the broker (or filer), importer of record, and the owner or consignee, where applicable. The notice will specify the nature of the violation charged and will designate the place and period of time during which the owner or consignee (or authorized representative) can provide oral or written testimony as to the admissibility of the article.

You will find additional information on FDA import procedures in FDA's Regulatory Procedures Manual, Chapter 9 Import Operations/Actions available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179264.htm

If you have questions regarding the detention or would like to discuss how to bring the devices into compliance, you should contact the FDA District Office at the port of entry. The FDA District Office directory is available on the Internet at http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm.

49. Q. Is the importer required to report adverse events to FDA and to the manufacturer?

A. Yes. Under the Medical Device Reporting regulations (21 CFR 803), importers must report to FDA and provide a copy of the report to the manufacturer if one of the importers marketed devices may have caused or contributed to a death or serious injury. 21 CFR 803.40. Such report must be submitted as soon as practicable, but not later than 30 days after the importer receives or otherwise becomes aware from any source of such information. Similarly, the importer must report to the manufacturer if one of the devices marketed by the importer has malfunctioned and such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious

injury if the malfunction were to recur. 21 CFR 803.40. The report must be submitted on Medwatch Form 3500A, 21 CFR 803.40. You can find additional information on Medical Device Reporting at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Optical Laboratories and Retail Stores

50. Q. Are there regulatory requirements for optical laboratories that surface (optically shape lens) perform edge cutting, or cast/mold lenses to a specific individual prescription?

A. U.S. optical laboratories that meet the definition of "manufacturer" must comply with all applicable provisions of the Federal Food Drug & Cosmetic Act. However those laboratories whose major responsibility is to render a service necessary to provide the consumer with a device or the benefits to be derived from the use of a device are exempt from registration under 21 CFR 807.65(i). Foreign optical laboratories, however, are not exempt from registration under 21 CFR 807.65. 21 U.S.C. 807.40. Foreign optical laboratories must submit an Establishment Registration and Device Listing (21 CFR 807.40(a) and 807.22) using FDA's Unified Registration and Listing System (FURLS). Foreign manufacturers must also provide the name, address, and phone number of their U.S. Agent (21 CFR 807.40(b)). Instructions on how to register, list and information about U.S Agent requirements are available on the Internet at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm.

All manufacturers (as referenced in Question #21) of impact resistant lenses for eyeglasses or sunglasses and of finished eyeglasses or sunglasses, including importers of such lenses and glasses, must follow the Quality System regulation (21 CFR 820) and report adverse events under Medical Device Reporting (21 CFR 803). Optical laboratories are exempt from Medical Device Reporting under 21 CFR 803.19(a)(3).

51. Q. Do the impact test regulations apply to retail stores that fabricate lenses?

A. FDA considers retail stores that fabricate lenses by coating and/or surfacing to be manufacturers of impact-resistant lenses. Therefore, such retailers must document impact resistance (21 CFR 801.410(c)(3)). You may perform impact testing on site or you may contract with a third party testing lab. Retail stores that only perform edging are not considered manufacturers.

Dispensing Untested Lenses

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

A. You may dispense lenses that are not impact resistant when a physician or optometrist determines that impact-resistant lenses will not fulfill the visual requirements of a

particular patient. The physician or optometrist must direct this in writing and give written notification to the patient (21 CFR 801.410(c)(1)).

53. Q. May a retailer supply a nonimpact-resistant lens if a patient requests it or if the patient/customer agrees to assume all responsibility?

A. You may only provide nonimpact-resistant lenses when the physician or optometrist determines that impact-resistant lenses will not fulfill the visual requirements of the patient. 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. 21 CFR 801.410(c)(1).

54. Q. What are some reasons a physician or optometrist may prescribe nonimpact-resistant lenses for a patient?

A. Physicians or optometrists may invoke the special exemption provisions of the regulation based on professional judgment. For example, a 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, and pressure sores. The physician or optometrist may determine that the visual requirements of the patient cannot be met by use of impact-resistant lenses.

55. Q. Are there situations in which a retailer may provide nonimpact-resistant lenses?

A. FDA believes it is appropriate to exercise its enforcement discretion with respect to a retailer who provides nonimpact-resistant lenses in an emergency situation with the knowledge and consent of the patient and the eye care professional. For example, a surgeon's eyeglasses break just before a scheduled surgery and the lenses need to be replaced immediately. If there is no alternative, FDA would consider exercising enforcement discretion with respect to a retailer who may provide the surgeon with nonimpact-resistant lenses on a temporary basis with the knowledge and consent of the patient and eye care professional.

Frames and Designs

56. Q. What are the FDA's requirements for the physical properties of lenses or the design of lenses?

A. The regulation requires only that lenses be made impact resistant and are impact tested. FDA has no other device specific property or design requirements imposed on lenses by regulation.

57. Q. Are there additional requirements for rimless eyewear?

A. No. Rimless eyewear must meet the same requirements as framed eyewear, including impact testing.

58. Q. What are the FDA regulations for spectacle frames?

A. A spectacle frame is a device made of metal or plastic intended to hold prescription spectacle lenses worn by a patient to correct refractive errors. Spectacle frames are regulated as Class I medical devices classified under 21 CFR 886.5842. They are exempt from Premarket Notification (510(k)). You can find the regulatory requirements for spectacle frames in "Sunglasses, Spectacle Frames, Spectacle Lens and Magnifying Spectacles" 21 CFR 886.5842 - 886.5850.

Labeling

59. Q. What are the labeling requirements for sunglasses or eyeglasses?

A. General labeling requirements can be found in 21 CFR 801.1 - 801.16 and can be accessed on the Internet at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/showCFR.cfm?CFRPart=801.

60. Q. Can labeling for sunglasses or eyeglasses include the terms "shatterproof" or "shatter-resistant"?

A. Yes, provided that such a claim is truthful and not misleading and meets all regulatory and statutory requirements for labeling and Premarket Notification. The terms "shatterproof" or shatter-resistant" are not equivalent to the term "impact resistant." Lenses that pass impact testing may be labeled as "impact resistant." Impact-resistant lenses may break or shatter under certain conditions. Impact-resistant testing does not demonstrate that the lens is either shatterproof or shatter-resistant. The manufacturer, therefore, should not make labeling claims such as "shatterproof" or "shatter-resistant" based solely on impact testing.

Additional Regulatory Requirements

61. Q. When would a Premarket Notification 510(k) be required for lenses or sunglasses?

A. Nonprescription sunglasses (21 CFR 886.5850), prescription spectacle lenses (21 CFR 886.5844), and magnifying spectacles (21 CFR 886.5840) are Class I devices and exempt from Premarket Notification 510(k). However, a 510(k) would be required if the device falls outside the limitations of the exemption (21 CFR 886.9). FDA would consider changes that could significantly impact safety or performance or that constitute a new intended use to be outside the limitations of the exemption, and thus, a submission of a 510(k) notification would be required.

You should submit a 510(k) when you have a health-related claim or performance-related claim that has not previously been cleared by FDA in a 510(k). The following are examples of the type of health-related claims that could require the submission of a 510(k): protects against the formation of cataracts, prevents cataracts and other ocular disorders, improves visual acuity, or treats color blindness. An example of a performance-related claim that could require a 510(k) is labeling that the lenses are "shatterproof." FDA would consider such statements as claims that go beyond those made by exempted legally marketed devices of that generic type.

Consumer Information

62. Q. Are eyeglasses and sunglasses safe to use for sports?

A. No. You should wear sports goggles that meet appropriate safety standards for the sport. You should not wear sunglasses or eyeglasses as personal protective equipment for sports or in situations requiring industrial safety lenses that could result in an impact to the face.

63. Q. Where can consumers report serious injuries related to medical devices?

A. Consumers may voluntarily report device-related deaths, injuries, and product problems to the Medical Device Reporting Office (MEDWATCH) of FDA. Consumers should use the MedWatch FDA Voluntary Form 3500 available on the Internet at http://www.fda.gov/Safety/MedWatch/default.htm to report problems. For information about a medical product, please call 1-888-INFO-FDA (1-888-463-6332). Written correspondence may be mailed to:

MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

APPENDIX A.

21 CFR 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.
http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=801&SECTION=410&TYPE=TEXT

APPENDIX B.

Drop Ball Test Unit (Impact Tester)
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm150003.htm

APPENDIX C.

Certification Statement of Impact Resistance

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm095296.pdf

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