

# **Impact-Resistant Lenses: Q&A - Vision Council Draft**

April 22, 2008 – Ken Wood

## **Impact-Resistant Lenses: Questions and Answers**

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### **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This draft guidance is a revision of “Impact-Resistant Lenses: Questions and Answers (FDA 87-4002),” issued September 1987. The revision reflects the exemption of sunglasses from the Premarket Notification (510(k)) requirement effective February 19, 1998. The revised document also includes a more detailed discussion about lens blanks, semi-finished, finished, and plano-power 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.

### **The Least Burdensome Approach**

This draft guidance document reflects our careful review of what FDA believes are the relevant issues related to impact testing on lenses and what FDA believes would be the least burdensome way of addressing these issues. If you have comments on whether there is a less burdensome approach, however, please submit your comments as indicated on the cover of this document.

## 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 impact-resistant 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)). Both monolithic and laminated glass and plastic 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, this 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. For consumers, there may be increased risk in continuing to wear scratched lenses because their impact strength may be 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/cdrh/ode/sunglass.pdf>.

For more information on this topic, you may contact the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) by phone at 240-276-

3150 or toll free, 800-638-2041, by fax at 240-276-3151, by e-mail at [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov), or write to the following address:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Communication, Education and Radiation Programs  
Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220)  
1350 Piccard Drive  
Rockville, Maryland 20850

## Prescription and Non-Prescription Glass Lenses

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

**A.** Every glass prescription lens must be impact tested after completion of all processing including coating, edging and tempering.

**2. Q.** What are the impact testing requirements for non-prescription (over-the-counter) glass lenses, e.g., magnifying spectacles and nonprescription sunglasses?

**A.** 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, including 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. 21 CFR 801.410(c)(3).

**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.** You must test a statistically significant sample of prescription and non-prescription plastic lenses from each production batch. The sample must be representative of the finished forms including lenses that are of minimal lens thickness. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form. This means that testing may be performed before or after edging or drilling the lens.

**5. Q.** Should you sell plastic-prescription lenses that have been used as part of the sample that was impact tested?

**A.** Performing the referee test on a lens does not reduce that lens' ability to withstand a second referee test. Therefore tested lenses may be sold if they do not have cosmetic flaws unacceptable in the market.

## Finished Lenses

**6. Q.** What is meant by “finished form” in 21 CFR 801.410(c)(3)?

**A.** FDA considers a lens to be in "finished form" when both surface and edging operations have been completed, and coatings and treatment for impact resistance has been applied, if appropriate. Lenses that have all processing completed except for edging and water bath tinting are called “uncut-finished lenses”.

## Lens Blanks (Semi-Finished Lens)

**7. Q.** What is a "semi-finished" lens?

**A.** A semi-finished lens is a partially manufactured lens with only one surface optically shaped and polished and left with extra material thickness to allow further processing to prescription. A semi-finished lens is a component of a medical device and is not a finished device.

**8. Q.** Is the manufacturer of semi-finished lenses required to perform the impact testing?

**A.** No. A semi-finished lens needs further processing that may weaken the lens. The entity that processes the semi-finished lens to the uncut-finished or finished form should test the lens after processing is complete.

## Plano-Power (Non-Corrective) Lens

**9. Q.** What is a "plano-power" lens?

**A.** A plano-power lens is a lens with no corrective power.

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

**A.** If retailers only edge and tint plastic lenses and do not perform processes identified as Manufacturing in Question 21, they need not test. In the case of glass lenses, the retailer who edges and treats the lens for impact resistance must test the lens regardless of its optical power.

## Sunglasses

**11. 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. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form. 21 CFR 801.410(c)(3).

**12. 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, and 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 with which they are intended to be worn.

## **Novelty and Children's "Toy" Sunglasses**

**13. 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)<sup>1</sup>. 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.

**14. 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 above in response to Question #13.

If they meet the criteria outlined in response to Question #13, 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).

**15. 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 as promotional items, they must meet the impact test (21 CFR 801.410).

<sup>1</sup> 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.

## Other Lens Types

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

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

**17. Q.** What regulations apply to industrial safety lenses?

**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.

**18. Q.** What regulations apply to sports goggles, such as skiing, swimming, and ball sports?

**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.

**19. 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.

**20. 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. Precautions should be taken 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 display 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 provide 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**

**21. 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)). In this document the word Manufacturer is capitalized to indicate the following definition applies. The Manufacturer is identified by the processing performed on the lens and not by business type or category. Manufacturer is defined under 21 CFR 820.3(o) as any person who designs, manufactures, fabricates, assembles, or processes a finished device. For the purposes of 21 CFR 801.410 this means the Manufacturer is the entity who alters the physical or chemical characteristics of the lens with actions such as grinding, polishing or coating of the optical surfaces, as well as heat treating and chemical tempering. Entities that perform any of these processes are manufacturers. Edging and tinting of plastic lenses has been shown to not significantly affect impact resistance when using the Referee test; therefore the regulation allows testing to be conducted before or after these operations.

In the case of plastic prescription lenses and all plastic non-prescription lenses, the entity that last processes the uncut-finished lenses prior to edging and mounting in a frame is the Manufacturer under this regulation. Since each lens may be processed by more than one Manufacturing entity, each such entity must test lenses for which they may be the final Manufacturer.

In the case of glass prescription lenses, the entity that produces the finished-edged lens and treats it for impact resistance following edging is the Manufacturer.

The entity that produces semi-finished lens blanks that require surfacing before use is not the Manufacturer as defined in this guidance and need not assure compliance of such lenses with this regulation.

An entity that molds or casts uncut-finished plastic lenses is a Manufacturer of that lens until and unless a second entity subjects that lens to further processing that makes the second entity the Manufacturer.

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))

**22. Q.** When should lenses be tested for impact resistance?

**A.** You should test lenses when the manufacturing processes identified in Question 21 are complete. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form. This means these lenses may be tested either before or after edging.

**23. 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 imported lenses.

**24. Q.** Should retail laboratories perform impact-resistant testing?

**A.** If a retail laboratory performs any manufacturing process identified in Question 21, they are a Manufacturer and must comply with all provisions of the regulation including testing.

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

**A.** A "Certification Statement of Impact Resistance," is a written statement in which the Manufacturer guarantees that the lenses in that batch have been tested and are impact resistant in accordance with this regulation. FDA may accept such a certification in lieu of test results, but upon request a Manufacturer must make the results available to the FDA as soon as practicable. Although a third party may do the testing and produce the certification statement for the tested batch, the Manufacturer issues the certification to the FDA. Suggested wording can be found in Appendix C.

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

**A.** A third-party testing service may conduct the impact test on a Manufacturer's lens batch and issue a certification of impact resistance to the Manufacturer for that batch. Although a third-party may conduct the testing, the name of the Manufacturer must be recorded on the Certification Statement as the certifier. The Manufacturer is the party responsible for meeting the requirements of this regulation. Third party testing should be performed in a timely manner to allow effective control of the impact resistance of each production batch.

Because there are significant differences between individual manufacturing sites including equipment, and related processes, third-party test services should not include processing of the lenses such that the impact resistance of the lenses can be affected. Instead, all lenses sent for third-party testing should be in the form such that the optically polished surfaces are completed by the Manufacturer. This is necessary because process variation from site to site can result in significant differences in lens impact resistance.

## **Testing Apparatus and Procedure**

**27. 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).

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

**A.** The regulation specifies a standard impact test referred to as the "Referee test". The industry often calls this the "drop-ball" test. This test sets the threshold for minimum lens impact resistance for dress eyeglasses and sunglasses as covered by this document.

A Manufacturer may test lenses using other methods that he judges to be equal or superior. However, if the FDA chooses to test the lenses the Referee test will be used.

The Referee test impacts the front surface of the lens with a steel ball, 5/8" in diameter, dropped from a height of 50 inches. The ball must strike within a 5/8-inch diameter circle located at the geometric center of the lens. If desired, the ball may be guided (but not restricted) in its fall by being dropped through a tube that extends to within approximately 4 inches of the lens. FDA will use this test exactly as written if they test lenses. The guide tube is optional. Although the regulation does not specify any means to hold the lens in place while it is struck, you may use any method that does not compromise the test. Because cosmetic damage may occur as a result of testing, an aid that holds the lens in place may be useful. For the same reason, a 3 mil (0.003") thick poly bag or film may be slipped over the lens for testing. If FDA tests they will not use any hold down device or the poly bag.

The lens support tube may be of any rigid material. Its diameter and the contour of the end that supports the lens may be altered, if necessary, to support the lens being tested. A 1/8" square neoprene gasket with a nominal hardness of 40 Durometer must be glued to the end of the tube supporting the lens. The neoprene distributes the impact load and cushions the lens.

Because the lens holder for the drop-ball test must be rigid, a substantial base is specified. The base must be made of ferrous metal and weigh a minimum of 27 lbs. The lens support tube is of any rigid material with 1" inside diameter with a 1/8" wall thickness and a length of about 1". For lenses of small minimum diameter, a support tube having an outside diameter of less than 1-1/4 inches may be used. The diameter or contour of the lens support may be modified as necessary so that the 1/8- by 1/8-inch neoprene gasket supports the lens at its periphery.

**29. 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 normal use).

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

**30. 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.

**31. 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.

**32. 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 should 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.

**33. 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.

**34. 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 45 for exempt lenses.

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

Semi-finished lenses are components used in creating a finished lens. Under 21 CFR 801.410, entities producing semi-finished lenses are not obligated to test these lenses in finished form for the purpose of determining a minimum thickness. However, these entities should assist subsequent Manufacturers by communicating any impact resistance conclusions regarding the processing of their semi-finished lenses into finished uncut or edged form. Such conclusions may include recommendations on minimum thickness and coatings. Because processes may be different at subsequent Manufacturers, this advice can only be a guide to help Manufacturers meet the requirements of 21 CFR 801.410.

- 36. 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. If FDA tests the lenses they will use the Referee test.

## Sampling Plans

**37. Q.** What constitutes a "batch"?

**A.** The regulation requires testing of all non-prescription lenses (including glass 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 quantity of lenses which are similar in nature, and such that prompt and effective investigation can be performed 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.

A batch may be defined by time or other parameters. For Manufacturers who produce a large variety of individually prescribed lenses, each with varying characteristics, a time-based batch including impact resistant lenses of all types may be suitable. For these manufacturers, the testing sample should contain appropriate proportions of the combinations of the different lens materials and coatings so that it is representative of the entire batch. Random selection of samples from all lens production in a specified time period is one acceptable method.

**38. 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 that is equal or superior.

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](http://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](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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD_IDENTIFICATION_NO=1585)

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. MIL-STD-105E is available on FDA's website in a letter to Manufacturers of sunglasses/eyeglasses at  
[www.fda.gov/cdrh/devadvice/21uuu.html](http://www.fda.gov/cdrh/devadvice/21uuu.html)

or directly at  
[http://www.fda.gov/cdrh/devadvice/MIL\\_STD\\_105E.pdf](http://www.fda.gov/cdrh/devadvice/MIL_STD_105E.pdf).

FDA will also accept use of a plan based on Lot Tolerance Percent Defective of 15%. Information on such plans may be found in ASTM E1994 - Standard Practice for Use of Process Oriented AOQL and LTPD Sampling Plans.

**39. Q.** How should lens samples be selected for testing using statistical methods?

**A.** Assuring lens impact resistance using statistical sampling means more than drop-ball testing a few lenses. How you select those test lenses and how you respond to any failures are critical parts of any testing program.

All Manufacturers must test plastic lenses on a batch sampling statistical basis. The Manufacturer has the option to test every lens and not use sampling methods. When using statistical sampling, each Manufacturer must draw samples from his entire batch on a regular basis. This is necessary because variation in materials and in processes such as surfacing and coating can result in significant changes in impact resistance. Testing should be done promptly on each production batch to allow effective control of the impact resistance of each production batch. If a batch includes lenses produced at multiple Manufacturing sites, the samples must be statistically representative of each site's production.

The lenses selected for testing must provide statistically significant representation of the total production from a single manufacturing site to confidently predict that all production lenses are capable of passing the impact test. The sample lenses must include forms that are of minimal lens thickness used by the Manufacturer and have been subjected to any treatment used to impart impact resistance.

All plastic prescription lenses and all non-prescription lenses of any material, when tested using statistical sampling methods, may be tested in the uncut-finished form before edging, or in the finished-edged form as ready to mount in a frame. This is allowed because for these plastic lens types, edging and tinting are not significant factors in determining lens impact resistance as measured using the Referee test.

The exempt lens types are: raised multifocal [Ref 4], 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.

**40. Q.** If an entity that processes impact resistant lenses, including optical wholesale or retail laboratories, has multiple locations, can testing lenses from one location for impact resistance cover all locations for compliance with the regulation?

**A.** Your testing must include statistically significant samples of all impact resistant lenses from each location involved.

**41. Q.** If a Manufacturer's lens production fails impact testing even when it is processed in accordance with the original manufacturer's recommendations, should the Manufacturer notify the original supplier of semi-finished lens blanks?

**A.** Manufacturers should manufacture and process lenses in accordance with the Quality System regulation under 21 CFR 820. If repeated failures occur, the Manufacturer must immediately investigate the cause and evaluate its process control. If repeated failures continue, the Manufacturer should request help from the entity who supplied the semi-finished lens blank.

## Records

**42. 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).

**43. Q.** What records are manufacturers required to maintain?

**A.** Manufacturers are required to maintain the records referenced above (Question #42). 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)).

**44. 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**

**45. Q.** What lenses are exempt from the impact test?

- A.** The following special lenses must be impact resistant but are exempt from testing:
- a. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing.
  - b. 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**

**46. 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 #25). 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 lens blanks require further processing in order to become a finished medical device. Under these



circumstances, the U.S. finished device manufacturer who does that processing 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.

**47. 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.

**48. 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.

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

**A.** Samples that are tested are not returned to the importer. If requests are made to a District Office for the return of any samples, FDA tries to comply with the requests.

**50. 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/ora/compliance\\_ref/rpm\\_new2/ch9/default.htm](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9/default.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/ora/inspect\\_ref/iom/iomoradir.html](http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html).

**51. 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/cdrh/devadvice/351.html>.

## **Optical Laboratories and Retail Stores**

**52. Q.** Are there regulatory requirements for optical laboratories that surface lenses and perform edging?

- A. U.S. optical laboratories, including those providing retail and/or wholesale service, must comply with all provisions of 21 CFR 801.410 if they are a Manufacturer as defined in Question 21.

U.S. optical laboratories are exempt from registration under 21 CFR 807.65(i). Foreign optical laboratories, however, must submit an Establishment Registration form FDA 2891 and Device Listing form FDA 2892 (See 21 CFR 807.40(a) and 807.22). Foreign manufacturers must also provide the name, address, and phone number of their U.S. Agent

(21 CFR 807.40(b)). Instructions and forms for registration and listing and information about U.S Agent requirements are available on the Internet at <http://www.fda.gov/cdrh/devadvice/>.

All Manufacturers, as defined 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).

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

**A.** FDA recognizes that some retail stores perform Manufacturing processes identified in Question 21. Such retail stores are Manufacturers and must meet all requirements of Manufacturers including testing for 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 perform only edging and/or water bath tinting of lenses are not Manufacturers.

## Dispensing Untested Lenses

**54. 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)).

**55. 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.** No. 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).

**56. 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.

**57. 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 Lens Designs

**58. 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.

**59. Q.** Are there additional requirements for rimless eyewear?

**A.** No. Rimless eyewear must meet the same requirements as all other eyewear, including impact testing.

**60. Q.** What are the FDA regulations for spectacle frames?

- A.** A spectacle frame is a device intended to hold spectacle lenses. 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" on the Internet at <http://www.fda.gov/cdrh/devadvice/21uuu.html>

## Labeling

**61. 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>.

**62. 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**

**63. 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**

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

**A.** The term ‘sport’ includes a wide range of activities. Some sports present significant eye and face hazards and in such situations impact resistant dress eyewear should not be worn for protection. You should wear sports goggles that meet appropriate safety standards for the sport. You should not depend on sunglasses or eyeglasses as personal protective equipment in situations that could result in an impact to the face.

**65. 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/medwatch/> to report problems. Consumers may also report problems to FDA by calling 1-800-FDA-1088 or 240-276-3001. For information about a medical product, please call 1-888-INFO-FDA (1-888-463-6332). Written correspondence may be mailed or faxed to:

FDA/CDRH/Medical Device Reporting

P.O. Box 3002

Rockville, MD 20847-3002 Fax: 240-276-3022 or 240-276-3023

**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.** Photograph of Drop Ball Test Unit (Impact Tester)

<http://www.fda.gov/cdrh/devadvice/dropball.html>

**APPENDIX C.** Certification Statement of Impact Resistance

<http://www.fda.gov/cdrh/devadvice/21uuua.html>

**APPENDIX D.** Definitions for terms used in this guidance document

# **APPENDIX D**

## **Definitions for terms used in this guidance document**

1. Manufacturer
  - a. The Manufacturer is identified by the processing performed on the lens and not by business type or category. The Manufacturer is the entity who alters the physical or chemical characteristics of the lens with actions such as grinding, polishing or coating of the optical surfaces, as well as heat treating. Edging and tinting of plastic lenses has not been shown to affect impact resistance when using the Referee test. Therefore the regulation allows testing to be conducted before or after these operations.
  - b. For the purpose of this regulation the term ‘Manufacturer’ also includes companies that import eyeglasses for resale.
  - c. In the case of plastic prescription lenses and all plastic non-prescription lenses, the entity that last processes the uncut-finished lenses prior to edging and mounting in a frame is the Manufacturer under this regulation. Since each lens may be processed by more than one Manufacturing entity, each such entity must test lenses for which they may be the final Manufacturer.
    - i. The entity that produces semi-finished lens blanks that require surfacing before use is not the Manufacturer as defined in this guidance and need not assure compliance of such lenses with this regulation.
  - d. In the case of glass prescription lenses, the entity that produces the finished-edged lens and treats it for impact resistance following edging is the Manufacturer.
  - e. An entity that molds or casts uncut-finished plastic lenses is a Manufacturer unless another entity subjects that lens to further processing that makes it the Manufacturer.
2. Lens
  - a. A device intended to correct optical errors of the human eye and that may also provide protection against sun glare.
3. Plastic lens
  - a. A lens made of any organic material. Generally this is any lens not made of glass.
4. Glass lens
  - a. A lens made of glass
5. Glass-plastic laminated lens
  - a. A lens made of both glass and plastic optical elements, cemented or otherwise bonded together.
6. Prescription lens
  - a. A lens with optical power designed to provide the optical correction prescribed by an ophthalmologist or optometrist.

7. Non-prescription lens
  - a. Any lens not manufactured to prescription. Such a lens may have optical power as in the case of over-the-counter (also known as Ready Readers or Magnifying Spectacles) reading glasses.
8. Semi-finished lens
  - a. A partially manufactured lens with only one surface optically shaped and polished and the other surface left with extra material thickness to allow further processing to prescription. A semi-finished lens is a component of a medical device and not a finished device.
9. Uncut-finished lens
  - a. This is a lens surfaced and polished on both surfaces to provide the prescribed optical power. The lens is not yet edged for mounting in the frame.
10. Finished-edged lens
  - a. A lens ready to mount in the frame with all processing complete including edging to the shape of the frame.
11. Edging
  - a. The process of removing excess material from the outer edge of the lens so that the lens is shaped and sized to fit a frame.
12. Clip-on lenses
  - a. Clip-on lenses are subject to this regulation. However, FDA intends to exercise its enforcement discretion regarding impact testing based on the following factors:
    - i. Whether the clip-on lenses cannot be worn alone, but can only be worn with lenses that are impact resistant;
    - ii. Whether they are designed so that they may be worn only on the outside (side distal from the eye) of the prescription lenses;
    - iii. Whether the clip-on lenses are the same size or smaller than the prescription lenses upon which they are intended to be worn.
13. Demonstration lenses
  - a. Lenses temporarily fitted to frames for sales display or lenses used as separate demonstration pieces. These are non-prescription lenses and are not intended for sale or consumer use.
14. Novelty and toy lenses
  - a. Lenses sold or given away as novelties or toys may in some cases be required to meet this regulation and others.
15. Industrial and sports lenses
  - a. Lenses made to the requirements of other regulations or standards and intended to provide protection beyond that required for dress eyeglasses and sunglasses.
16. Tinting
  - a. Water bath tinting of plastic lenses, such that the lenses or coatings absorb dye or tint dissolved in warm water baths do not affect lens impact resistance. Tinting lens by means other than water bath can affect impact resistance and the entity performing such processing is a Manufacturer as defined in this guidance.



17. Coating Company/Coating Service
- a. A service provider that adds coatings to a lens surface. The following coatings may be applied both in combination and singularly: scratch resistant coatings, Tint coatings, Anti reflection coatings, hydrophobic and hydrophilic top coatings, mirror coatings, and others.
18. Sunglasses
- a. Sunglasses are spectacles that reduces solar glare and that may or may not have prescription lenses.
19. Dispenser
- a. Dispenser signifies an entity that releases the finished product to the end user. Dispensers do not alter the eyewear in such a way that the lenses ability to pass the referee test is affected. Dispensers are not Manufacturers; they simply pass-through eyewear that was manufactured by other entities.
20. Retail Store
- a. Retail Stores are those entities that sell finished spectacles in their final form to the general public.
  - b. A Retail store is not a Manufacturer unless it performs lens processes described in the definition of Manufacturer in Question 21 of this document.
21. Dress Eyewear
- a. Dress eyewear, also known as eyeglasses, are spectacles worn on a daily basis by the general public at home, at work or at play; where safety eyewear, sport eyewear, industrial eyewear, or other elevated levels of protection are not required.
22. Batch
- a. A group of lenses representing a Manufacture's production of all impact resistant lenses.
23. Magnifying Spectacles
- a. Also know as Readers, or Ready Readers. These glasses have corrective power but can be purchased by the public in retail settings without an Rx.
24. Dark Colored Lenses
- a. Lenses with a tint darker than a fashion tint and intended to reduce the transmission of visible light.
25. Eyeglasses
- a. Eyeglasses, also know as Dress Eyewear, is that eyewear intended for daily use at home, at work or at play; where safety eyewear, sport eyewear, industrial eyewear, or other elevated levels of protection are not required.