Guidance for Industry

Guidance Document For Nonprescription Sunglasses

Document issued on: October 9, 1998

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

Division of Ophthalmic Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to David M. Whipple, Associate Director, Division of Ophthalmic Devices, HFZ-460, 9200 Corporate Blvd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact David M. Whipple at (301) 594-2205

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World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/sunglass.pdf, or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 2208 when prompted for the document shelf number.

Table of Contents

Introduction

In the United States, nonprescription sunglasses are regulated as medical devices by the Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration (FDA). It is estimated that over 300 million sunglasses are distributed in this country every year, making them one of the most widely available over-the-counter ophthalmic devices regulated by FDA. In addition, there are hundreds of manufacturers, importers and distributors of sunglasses who are ultimately responsible for assuring that the regulatory requirements applicable to nonprescription sunglasses are being met. The enclosed guidance document was developed to assist these individuals in meeting their regulatory responsibilities.

Nonprescription sunglasses are classified and regulated by FDA as class I devices in accordance with section 886.5850 in Title 21 of the Code of Federal Regulations (CFR). Section 206 of the FDA Modernization Act (FDAMA) of 1997 added, among other provisions, section 510(l) to the Act. This provision became effective on February 19, 1998. Section 510(l) states that submission of a report (i.e., premarket notification) to FDA under section 510(k) is not required for class I devices unless the class I device is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA does not believe that nonprescription sunglasses are a type of device that meets the criteria outlined above for submission of a premarket notification under section 510(k). On February 2, 1998, FDA published a notice in the *Federal Register* (63 FR 5387) identifying nonprescription sunglasses as a device type that should be exempt from premarket notification. The exemption for nonprescription sunglasses became effective on February 19, 1998.

FDA believes that this deregulation action is appropriate and consistent with current agency policy for using the least burdensome approach for regulating medical devices with minimal risks such as those historically associated with sunglasses. This deregulation step, however, does not mean that sunglasses are exempt from any other statutory or regulatory requirements, unless an order or regulation issued by FDA explicitly provides such exemptions. Indeed, FDA's determination that premarket notification was unnecessary to provide a reasonable assurance of safety and effectiveness for nonprescription sunglasses is based, in part, on the assurances provided by other regulatory controls. Nonprescription sunglasses remain subject to regulations such as those identified as "general controls", which are applicable to all class I devices, and impact resistant lens requirements. In addition, there are limitations placed on the exemption of nonprescription sunglasses, as described in 21 CFR 886.9 and in the February 2, 1998 *Federal*

Register notice. To avoid unnecessary or inadvertent violations of the Act, the limitations of the exemption must be clearly understood prior to marketing sunglasses in the United States without a determination of substantial equivalence from FDA through the 510(k) process.

FDA is issuing this guidance document for nonprescription sunglasses for purposes of (1) informing manufacturers, importers, distributors and other interested persons of the new regulatory changes affecting these devices; (2) identifying applicable regulations and voluntary performance standards associated with the manufacturing and marketing of nonprescription sunglasses; and, (3) providing guidance on the interpretation of the limitations of the exemption for Class I devices as it relates specifically to nonprescription sunglasses.

We hope you find this document to be useful and informative. We welcome your comments and requests for further information on the regulation of nonprescription sunglasses.

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Guidance Document
For Nonprescription Sunglasses

I. Scope:

This guidance is provided to the manufacturers, distributors, importers and other interested persons to assist them in understanding the regulatory requirements of the Food and Drug Administration (FDA) that are applicable to nonprescription sunglasses. This guidance applies to all Class I nonprescription sunglasses, including clips (clip-ons), that are usually marketed as over-the-counter (OTC) devices and worn in conjunction with casual or fashion dress and during general recreational activities.

This guidance does not apply to industrial eyewear, prescription eyewear, ready-to-wear reading glasses, sport protective eyewear or other forms of eyewear not defined as nonprescription sunglasses in this guidance. In addition, this guidance does not attempt to address additional laws and regulations enforced by other federal agencies that may also be applicable to nonprescription sunglasses (e.g. country of origin marking requirements pursuant to 19 USC Section 1304 of the United States Tariff Act of 1930). Manufacturers, importers and distributors of nonprescription sunglasses are expected to be aware of and comply with all laws and regulations, including those enforced by FDA, that are applicable to their device.

NOTE: For purposes of this guidance, the terms “nonprescription sunglasses” and “sunglasses” may be used interchangeably.

II. Definitions:

This section of the guidance includes terms and definitions that are applicable to nonprescription sunglasses. This is by no means an all-inclusive list of terms used within this guidance to describe the regulation of nonprescription sunglasses. They are provided as a ready reference source for understanding and interpreting the information provided in this guidance. [See **Annex C**- Bibliography for an informative list of references (e.g., laws, regulations and standards) that are applicable to nonprescription sunglasses and where relevant terms and definitions are located].

a. Manufacturer: any person who designs, manufactures, fabricates, assembles, or processes a finished device. The term includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification

development, and initial distributors of foreign entities performing these functions. [21 CFR 820.3 (o)]

b. Wholesale Distributor: any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user. [21 CFR 807.3 (s)]

c. Initial Importer: any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. [21 CFR 807.3 (g)]

d. Class I Device: the class of a devices that are subject to only the general controls authorized by or under Sections 501 (adulteration), 502 (misbranding), 510 (registration), 5 16 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the Act. [21 CFR 860.3 (c) (1)]

e. Nonprescription Device (ophthalmic): an ophthalmic medical device that is marketed directly to the end user (i.e., consumer) without the need for a prescription or any other order issued by a licensed eyecare practitioner.

NOTE: Nonprescription devices are commonly sold or distributed as "over-the-counter" (OTC) devices. [21 CFR 801 - Subpart C]

f. Nonprescription Sunglasses: ophthalmic medical devices consisting of spectacle frames and spectacle lenses or clips (clip-ons) intended for use in the attenuation of sunlight but not intended to provide refractive corrections. [21 CFR 886.5850]

g. Exempt Device (ophthalmic): a type of ophthalmic device that FDA has granted an exemption from the requirement of premarket notification under section 510(k) of the Act and subject to the limitations of exemptions as described in the ***Federal Register*** (FR) announcement dated February 2, 1998 and titled, "Medical Devices; Exemptions from Premarket Notification and Reserved Devices; Class I." [63 FR 5387]

NOTE: Ophthalmic devices that are exempt from premarket notification [510(k)] can be located in 21 CFR PART 886.

h. Label: a display of written, printed or graphic material upon the immediate container of any device. [Section 201(k) of the Act]

i. Labeling: all labels and other written, printed or graphic material that is (1) upon any article (device) or any of it's containers or wrappers; (2) accompanying such article (device) at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce. [Section 201(m) of the Act]

III. Regulatory Status of Nonprescription Sunglasses:

Nonprescription sunglasses are:

a. described in 21 CFR Section 886.5850 as devices that consist of spectacle frames or clips (clip-ons) with absorbing, reflective, tinted, polarizing or photosensitizing lenses intended to be worn by a person to protect the eyes from bright sunlight but not to provide refractive corrections;

b. classified as Class I medical devices (product code HQY) and regulated under the general controls provisions of the Act; and,

c. exempt from the requirement of premarket notification [510(k)] effective February 19, 1998 in accordance with Section 206 of the FDA Modernization Act (FDAMA) of 1997. In addition, nonprescription sunglasses are subject to the limitations of exemptions as described in the *Federal Register* notice dated February 2, 1998 and titled, "Medical Devices; Exemptions from Premarket Notification and Reserved Devices; Class I." [63 FR 5387]

NOTE: Sunglasses that do not meet the criteria for compliance with the limitations of exemptions must submit a 510(k) and receive a determination of substantial equivalence from FDA before marketing the device (See **Annex A** for Guidance on the Limitations of Exemptions for Nonprescription Sunglasses).

IV. Manufacturing Information:

When establishing finished product specifications for sunglasses, manufacturers should assess the following physical, chemical, optical and toxicological properties of the major components (i.e., spectacle frames and/or spectacle lenses) used in the manufacturing of the finished device:

a. Impact Resistance: Sunglasses **shall** be fitted with impact-resistant lenses. Impact-resistant lenses **must** comply with FDA requirements set forth in 21 CFR 801.410, Use of Impact Resistant Lenses in Eyeglasses and Sunglasses.

NOTE: Use of the words **must** and **shall** is appropriate in a voluntary guidance when a manufacturer is ordered to comply with a requirement established by law or regulation.

b. Flammability: Sunglasses should be manufactured from finished materials that are nonflammable as defined in the Federal Hazardous Substances Act [15 U.S.C. 1261 (f)]. Meeting the flammable solids requirements of 15 USC 1261~1, 1263 and 16 CFR 1500.44 would be considered adequate for purposes of addressing this specification.

c. Biocompatibility: Sunglasses should be manufactured from finished materials that are non-toxic, non-irritating, nor capable of producing allergic reactions to a significant degree under normal conditions of use.

d. Optical Properties: Sunglasses should be manufactured with plano spectacle lenses designed to attenuate sunlight and provide the optical characteristics or properties as stated in the labeling, advertising, or promotional materials for the device (e.g., polarizing, ultra violet (UV) blocking, tinted, reflecting. etc.)

Conformance with the requirements of the following voluntary national or international standards, e.g., American National Standards Institute (ANSI), International Organization of Standards (ISO), is considered acceptable for good manufacturing practices and appropriate for use in evaluating the critical design characteristics and properties listed above.

a. Impact Resistance: ANSI Z80.3-1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements, Section 5.1- Impact Resistance Test

b. Flammability: ANSI Z80.3-1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements Section 5.3 - Flammability Test

c. Biocompatibility: ISO 10993, Biological Evaluation of Medical Devices - Parts 1-12

d. Optical Properties:

- ISO 14889, Ophthalmic Optics - Fundamental Requirements for Uncut Spectacle Lenses, Section 4.5.

- ISO 8980 - 3, Ophthalmic Optics -Uncut Finished Spectacle Lenses - Part 3, Transmittance Specifications and Test Methods.

- ANSI Z80.3 - 1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements, Sections 4.4 through 4.8.

NOTE 1: The standards cited under "Optical Properties" (Subsection d) above may be used to determine refractive properties, transmittance properties including traffic signal recognition and other optical properties identified within these standards that may be applicable to the design of the device.

NOTE 2: Traffic Signal Recognition provisions contained in ANSI Z80.3 were developed with the color defective person in mind. Approximately 8% of the male population and less than 3% of the female population have some type of color deficiency. Therefore, some of the requirements of this section of the standard may be overly stringent for color normal individuals.

V. Label and Labeling Information:

The terms label and labeling are related but not interchangeable. The term "label" is more restricted in scope and generally consists of the part of the display that is confined to the device itself. The term "labeling" is much broader in scope and consists of the label on the devices as well as the descriptive and informational literature that may accompany the device, or may come together at the device's point of display. The following is a list of labeling regulations that are generally applicable to nonprescription sunglasses.

a. General Labeling Requirements:

Nonprescription sunglasses are generally marketed as OTC medical devices and are subject to the following general labeling and OTC labeling requirements outlined in 21 CFR Part 801 - Labeling:

(1) Subpart A - General Labeling Provisions:

- Sec. 801.1 - Name and Place of Business;
- Sec. 801.4 - Intended Uses
- Sec. 801.5 - Adequate Directions for Use
- Sec. 801.6 - False and Misleading Statements
- Sec. 801.15 - Prominence of Labeling Statements

(2) Subpart C - Labeling Requirements for Over-the-Counter Devices

- Sec. 801.60 - Principal Display Panel
- Sec. 801.61 - Statement of Identity
- Sec. 801.62 - Declaration of Net Quantity

(3) Subpart D - Exemptions from Adequate Directions for Use

- Sec. 801.116 - Medical Devices Having Commonly Known Directions

(4) Subpart H - Special Requirements for Specific Devices

- Sec. 801.410 - Use of Impact Resistant Lenses in Eyeglasses and Sunglasses

b. Adulteration Laws:

Section 501of the Act contains provisions defining adulteration of devices. Specifically, 501(c) states a device is adulterated if its quality falls below that which it purports or is represented to possess. Violations may include non-compliance with an applicable regulation (e.g., non-compliance with impact resistant lens regulations), non-conformance with an applicable standard for which conformance is claimed (e.g., non-conformance with traffic signal recognition provisions of ANSI Z80.3 when conformance is stated or implied in the labeling) or any other implied or stated labeling claim that would cause the device to be adulterated within the meaning of Section 501 of the Act (e.g., claims made by the manufacturer in the labeling for their sunglasses that claim they are constructed of lenses that block 100% UVA, UVB & UVC if such statements are untrue with respect to the sunglasses in question).

c. Misbranding Laws

Section 502 of the Act contains provisions on misbranding and false or misleading labeling for medical devices. Specifically, section 502(a) declares that a device is misbranded if it's labeling proves to be false or misleading in any particular. Historically, OTC devices, such as sunglasses, are at risk for violations of this law because they are generally marketed directly to consumers. Violations of this law are not confined to strict interpretations of statements that are untrue, forged, fraudulent or deceptive. It may also include labeling that creates a false impression in the mind of a consumer. Examples of false or misleading labeling includes:

- unsubstantiated claims of therapeutic value;
- ambiguity, half-truths, and trade puffery;
- failure to reveal a material fact;
- inadequate, incomplete, or inaccurate statements
- deceptive pictorial matter

To avoid unnecessary or inadvertent violations of the Act, all promotion, labeling and advertising material should be carefully reviewed to insure compliance with the labeling laws and regulations applicable to nonprescription sunglasses (See **Annex B** for additional labeling guidance on intended use, performance claims, and directions for use specifically relating to nonprescription sunglasses).

Annex A

Limitations of Exemption for Nonprescription Sunglasses

Nonprescription sunglasses were granted an exemption from the requirement of premarket notification under section 510(k) of the Act on February 19, 1998. In addition, they are subject to the limitations of exemptions as described in 21 CFR 886.9 and in the February 2, 1998 *Federal Register* (FR) announcement titled, "Medical Devices; Exemptions from Premarket Notification and Reserved Devices; Class I." [63 FR 5387]

As previously stated in the cover letter of this guidance, Section 206 of the FDA Modernization Act (FDAMA) of 1997 added, among other provisions, section 510(l) to the Act. Section 510(l) states that submission of a premarket notification report to FDA under section 510(k) is not required for a class I device unless the device is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, hereafter referred to as "reserved criteria." FDA does not believe that nonprescription sunglasses are a type of device that meets the reserved criteria outlined above to require the submission of a premarket notification report under section 510(k). Therefore, on February 2, 1998, FDA published a notice in the *Federal Register* identifying nonprescription sunglasses as a device type that should be exempt from premarket notification. The exemption for nonprescription became effective on February 19, 1998.

FDA's decision to grant an exemption from the requirements of premarket notification for a generic type of device, such as sunglasses, is based upon existing and reasonably foreseeable characteristics of these devices. However, FDA cannot anticipate every change in the intended use of a device that is of substantial importance in preventing impairment of human health or changes in the device characteristics that significantly affects the safety or performance of the device as to present a potential unreasonable risk of illness or injury as described in the reserved criteria. Therefore, manufacturers of devices for which FDA has granted an exemption from premarket notification requirements must still submit a premarket notification [510(k)] to FDA and receive a substantial equivalence determination before introducing the device into interstate commerce for commercial distribution when:

a. The device has an intended use that is different from the intended uses of legally marketed devices in the generic type of device; e.g., a device that is intended for a different medical purpose, or a device that is intended for lay use instead of use by health care professionals; or,

b. The device has been modified to operate using a different fundamental scientific technology that differs from those used by legally marketed

devices in that same generic type of device, e.g., a surgical instrument that cuts tissue with a laser beam rather than with a sharpened metal blade.

Any class I device incorporating such changes or modifications is no longer considered exempt from premarket notification because FDA believes they would meet the reserved criteria described in section 510(l) of the Act.

The following examples provided below are presented to help illustrate FDA's interpretation of the limitations of exemptions as it specifically relates to nonprescription sunglasses.

Example 1 - FDA has previously cleared for marketing nonprescription sunglasses for use in relieving eye strain and eye fatigue due to glare from exposure to bright sunlight. FDA would consider manufacturers making similar types of sunglasses with a similar type of claim to be within the limitations of the exemption and no premarket notification [510(k)] would be required prior to placing the sunglasses into commercial distribution. Manufacturers are reminded, however, all claims must be supported by valid scientific evidence regardless of the need for submission of a 510(k).
Information supporting any marketing claims should be maintained by the manufacturer in the appropriate records for the device.

Example 2 - A manufacturer of sunglasses wants to make health related or other performance claims in their labeling that have not been previously cleared by FDA in a 510(k). These claims may include statements such as, "…for protection against the formation of cataracts…" or "…for prevention of cataracts and other ocular disorders…", "…improves visual acuity…", or "…for use in the treatment of color blindness…". Such statements would be considered claims of intended uses that are different from the legally marketed devices of that generic type. Therefore, sunglasses making such claims would not be exempt from premarket notification because they would met the reserved criteria described above, under section 510(l) of the Act.

The above examples are provided as guidance for interpretation of the limitations of exemptions as it specifically applies to nonprescription sunglasses. Past experience has demonstrated, however, that manufacturers of devices that have been granted an exemption from premarket notification [510(k)] submission requirements often assume they have achieved a greater degree of deregulation than the exemption affords. FDA advises that an exemption from the requirements of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless FDA issues

an order or regulation that explicitly provides such exemptions. Therefore, it is extremely important that all parties involved in the manufacturing and distribution of nonprescription sunglasses become thoroughly familiar with the limitations of exemption and with the other general controls that are applicable to all Class I devices. Familiarity with the laws and regulations applicable to nonprescription sunglasses will help manufacturers meet their regulatory responsibilities and avoid unnecessary or inadvertent violations of the Act.

In the past, FDA has taken exception to certain unsubstantiated performance claims or new intended uses, such as those relating to UV absorbing sunglasses, that have appeared in promotion, labeling and advertising from several manufacturers. Warning letters have been issued by FDA to manufacturers advising them that commercial distribution and promotion of a device with unsubstantiated claims and without the benefit of a determination of substantial equivalence through the 510(k) process may result in the adulteration of the device within the meaning of Section 501 and misbranding of the device within the meaning of Section 502 of the Act.

It is ultimately the responsibility of the manufacturer to determine if new or modified type of sunglasses meets the criteria for exemption from submission of a 510(k) prior to marketing and distribution in the United States. If a manufacturer is uncertain as to the regulatory status of their new or modified sunglasses, please contact the Division of Ophthalmic Devices, at the phone numbers previously provided in this document, for further advice and guidance relating to the limitations of exemptions for nonprescription sunglasses.

Annex B

Labeling Guidance for Nonprescription Sunglasses

Intended Use and Performance Claims:

Sunglasses are intended for use in the attenuation of bright sunlight. They are generally worn with casual or fashion dress, while driving during daylight or while participating in general recreational activities.

Sunglasses manufactured with reflective, tinted, polarizing, photosensitizing lenses and meet ISO 8980 - 3 or ANSI Z80.3 for UV and visible light transmittance requirements, may also be indicated for use in protecting the eyes from exposure to bright sunlight including it's UV component. The degree to which sunglasses will attenuate sunlight and block UV varies with the physical, chemical and optical properties of the lenses. Therefore, the performance claims found in the promotion, labeling or advertising for sunglasses may vary according to its construction. The following are examples of statements of intended use and performance claims that are adequate for labeling of nonprescription sunglasses:

a. Sunglasses that meet UV requirements of Table 4 of ANSI Z80.3-1996 may be labeled as follows:

   "…lenses meet ANSI Z80.3 1996 [normal] or [strictest] UV blocking requirements ".

   Additional optional language: "…lenses block [X]%UVB and [Y]%UVA."

b. Sunglasses constructed with absorbing, reflective, tinted, polarizing or photosensitizing lenses attenuate light and reduce glare. Therefore, sunglasses may be labeled with a claim such as:

   "…may reduce eye strain and / or eye fatigue due to glare".

c. Sunglasses that meet the FDA impact resistance requirements may be labeled with statements such as:

   "…lenses meet applicable government impact resistance requirements but ARE NOT SHATTERPROOF".

d. Sunglasses intended for driving should pass the requirements specified in ISO-14889, section 4.5 or ANSI Z80.3-1996, section 4.6.3, and may be labeled accordingly. Sunglasses that do not meet either of these requirements should be labeled:

"CAUTION: not for use while driving."

Directions for Use:

OTC nonprescription sunglasses can usually be marketed without comprehensive directions for use because their common uses are generally known to the ordinary individual (21 CFR 801.116). However, manufacturers may choose to include a section in their labeling to provide information on selection and use criteria for their sunglasses. An example of selection and use criteria are illustrated below:

a. Sunglasses are required by federal law to be impact resistant, but they are not shatterproof nor are they an unbreakable shield. They are not intended to function as impact protective eyewear for use in high-risk impact sports or for industrial safety uses.

b. Choose a lens shade with a relationship to use. Generally speaking, in and around town, the more cosmetic or light to medium tints are worn; while on the beach or skiing darker shades are worn. Ultimately, the amount of light a lens should transmit relates to the brightness of the environment and individual comfort.

c. In selecting sunglasses, test the optical quality of the lens by putting on the sunglasses and viewing a vertical edge or line. Do this by moving your head back and forth allowing your eyes to sweep across the lens. If there is any wiggle in the line, then the lens may have an optical defect and you should choose another pair.

d. The frame should fit comfortably and allow the lens to be positioned directly in front of the eye.

e. If you are uncertain that the sunglasses you intend to purchase meet traffic signal recognition requirements, read the labeling to determine if there are statements recommending that the sunglasses should not be worn while driving.

In addition, manufacturers may choose to include public service reminders of commonly understood risks associated with the misuse of sunglasses. Suggested reminders may include the following:

a. Tinted eyewear is not recommended to be worn for night driving.

b. Sunglasses are not intended for use as protection against artificial light sources, such as sun lamps, lasers, etc.

c. Sunglasses are not recommended for high-risk impact sports participants.

d. Sunglasses are not intended for use as industrial safety eyewear.

e. Never stare directly at the sun or at an eclipse with or without sunglasses.

f. Lenses in sunglasses must meet applicable federal requirements for impact resistance but they ARE NOT SHATTERPROOF.

Annex C

Bibliography of References for Nonprescription Sunglasses

Laws and Regulations:

- Code of Federal Regulations (CFR) Section 1500 44 (Flammability Requirements) (1998).

- Sections 501 (Adulterated Devices), 502 (Misbranded Devices), 510 (Registration), 510(k) (Premarket Notification), 516 (Banned Devices), 518 (Notification and Recall of Defective Devices), 519 (Device Reporting), and 520 (General Provisions, Good Manufacturing Practices) of the Federal Food, Drug and Cosmetic Act (FD&C Act), codified at 21 United States Code (USC) Sections 351, 352, 360, 360f, 360h, 360i and 360j, respectively.

- Section 206 of the FDA Modernization Act (FDAMA) of 1997 (amending Section 510(k) of the FD&C Act), PL. 105-115, 111 Stat. 2296, 2338, (Nov. 21, 1997).

- 21 CFR 801.1 to 801.16 (General Labeling Provisions), 801.116 (Labeling Exception), 801.410 (Impact Resistance "Drop Ball" Test), 807.20 (Registration and Listing), 820.3 (Quality System / GMP Requirements), 820.120 (Labeling Procedures), 886.9 (Limitations on 510(k) Exemptions), 886.5850 (Classification Regulation for Nonprescription Sunglasses) (1998).

- Sections 2 and 4 (Flammability Requirements) of the Federal Hazardous Substances Act codified at 15 USC Sections 1261 (f) and (l) and 1263, respectively.

- Medical Device Amendments Act, PL. 94-205, 90 Stat. 579 (May 28, 1976).

- Section 304, Tariff Act of 1930, codified at 19 USC Section 1304 (Country of Origin Marking).

- Notice, Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I, 63 *Federal Register* 5387 (February 2, 1998).

Voluntary National and International Standards:

- ANSI Z80.3-1996, Ophthalmic - Nonprescription Sunglasses and Fashion Eyewear Requirements.

- ISO 8980-3, Ophthalmic Optics - Uncut Finished Spectacle Lenses - Part 3 - Transmittance Specification and Test Methods.

- ISO 14889, Ophthalmic Optics - Spectacle Lenses - Fundamental Requirements for Uncut Finished Lenses.

- ISO 10993, Biological Evaluation of Medical Devices - Parts 1 through 12.