THE REGULATION OF SUNGLASSES & READING GLASSES

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AUTHORS:

Rick Van Arnam, Esq.
Legal Counsel, The Vision Council
rvanarnam@barnesrichardson.com

Michael C. Vitale, ABOM
Technical Director, The Vision Council
mvitale@thevisioncouncil.org

THE VISION COUNCIL

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This pamphlet has been created to provide an overview of many of the regulatory matters that may impact compliance with regulations and quality standards in the production and sale of sunglasses or reading glasses.

Several federal and some state regulatory agencies have jurisdiction over the regulation of non-prescription sunglasses and reading glasses, including: the FDA, Customs, Federal Trade Commission, Consumer Product Safety Commission, the Department of Agriculture, as well as specific reading glass regulations for state laws in four states. In addition, there are voluntary standards that have been adopted both nationally and internationally.

I. THE REGULATION OF SUNGLASSES AND READING GLASSES

A. U.S. FOOD AND DRUG ADMINISTRATION

The United States Food and Drug Administration (FDA) has jurisdiction over the Federal regulation of medical devices made or sold in the United States. Two such medical devices are non-prescription sunglasses and reading glasses.

Both devices are regulated as Class 1 medical devices. The FDA has exempted most Class 1 devices from filing a pre-market notification application, nor is FDA clearance required before marketing a Class 1 device in the U.S. Manufacturers and initial importers/distributors, however, must register their establishments with the FDA annually.

1. **Establishment Registration**
   - a) **FURLS**
     Establishment registration is done online through the FDA's Electronic Registration and Listing System, which is a web portal known as "FURLS." FURLS can be accessed at https://www.access.fda.gov/oaa/. Any establishment, whether located in the United States or abroad, involved in the production, importation or initial distribution of sunglasses or reading glasses to be marketed in the United States is required to register with the FDA, and to renew that registration annually.
   - b) **Who Must Register?**
     While the regulations are written to include a broad class of establishments (companies involved in the manufacture, preparation, propagation, compounding, assembly, or processing of a medical device for commercial distribution), this can be simplified into two groups:
   - (1) **Foreign or U.S. companies that manufacture sunglasses or reading glasses. This would include direct manufacturers, exporters, contract manufacturers, repackagers/ relabelers, and re-manufacturers.**
   - (2) **Initial distributors and importers. These businesses receive devices imported into the United States and further distribute them.**

A complete list of the different classes of establishments that must register can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm.

   - c) **Must I Pay?**
     Establishments should also check this list to determine whether or not they will owe the FDA the annual filing fee. The fee for 2016 is $3,845; in 2017 it is estimated to be increased to $3,872. As a general rule, if the establishment, either foreign or U.S., has to register then the fee will apply. Companies characterized as initial distributors or importers are no longer exempt from the fee.
   - d) **Annual Renewal**
     The fee is paid annually, during the annual renewal process. Every year between October 1st and December 31st, all registered establishments wishing to maintain an active status with the FDA must enter FURLS and renew their registration. This is true whether or not a fee is owed; if a fee is owed, it is paid at this time. If a company fails to renew, or chooses not to renew, then the establishment will be delisted from FURLS and that enterprise cannot legally manufacture, distribute or sell medical devices in the United States. Reviving a delisted establishment is a time consuming process, so electing not to renew, or failing to renew during the renewal period, can complicate business transactions that might come up during a period when you have been delisted.
   - e) **Official Correspondent**
     Each company registering with the FDA will need to designate an individual as the company's "official correspondent." Any communications from the company to the FDA must be initiated by the official correspondent, so companies should select as their official correspond someone with authority to discuss issues with the FDA. Please note that the official correspondent differs from the official U.S. Agent, which is discussed later.

2. **Device Listings**
   a) **What Must be Listed?**
   Manufacturers of medical devices are required to file a medical device listing for each medical device they produce. Therefore, companies must file a separate device listing for sunglasses and reading glasses if they manufacture those devices. New device listings are done on line through FURLS, and device listers are required to update their existing devices as part of the annual registration process.
   b) **Who Must List?**
   Manufacturers of medical devices are required to file a medical device listing. Companies that characterize themselves as initial importers or distributors do not need to list the devices they import or distribute. This is true even though initial importers or distributors must register their establishments with the FDA. Initial importers, however, must identify their manufacturers.
3. **U.S. Agent**
   a) **Definition of a U.S. Agent**
   All foreign establishments required to register with the FDA must designate a U.S. Agent. The U.S. Agent is responsible only for 1) assisting the FDA in communicating with the foreign establishment; 2) responding to FDA questions concerning the foreign establishment's products that are imported and offered for sale in the United States, and 3) assisting the FDA in scheduling an inspection of the foreign establishment.
   b) **What's the Difference between a U.S. Agent and Official Correspondent?**
   If the foreign establishment needs to inquire of the FDA, then this communication must originate from the company's "official correspondent," not its U.S. agent. As discussed above, the official correspondent is the individual designated by the company in its FDA registration as the spokesperson for the company. The FDA will not address any inquiry put to it by anyone who is not the official correspondent of the registrant.
4. **Impact Resistant Lens and the Impact Resistant Statement**
   a) **Requirement for Impact Resistant Lenses**
   Sunglasses and reading glasses must be fitted with impact resistant lenses. The requirements for impact resistance are set out at 21 C.F.R. 801.410. These requirements are also set out in the American National Standards Institute's ("ANSI") voluntary standard, Z-80.3-2015. In 2010, the FDA also updated its guidance document covering impact resistance, and this document is a useful guide to understanding the requirements for testing lenses for impact resistance.
   b) **Certification of "Drop Ball" Test**
   Each shipment into the U.S. must be accompanied by certification that the lenses, whether loose or mounted, comply with the FDA's impact resistance regulations. The "drop ball" test is set out in the FDA's regulations, and the certification must state that the imported eyewear was tested for, and passed, impact resistance. If a drop ball certificate does not accompany a shipment, then the FDA is authorized to hold and then detain the shipment. At this point, the impacted parties will have to petition to have the merchandise released, with no guarantee that the shipment will be released into the commerce of the United States.
   c) **Actual Test Data**
   Importers of sunglasses and reading glasses should also note that even when a drop ball certificate accompanies a shipment the FDA has the right to request the actual test data underlying that certificate. In these situations the importer and the manufacturer will be given the opportunity to provide the supporting data, and if found to be sufficient, get release of the merchandise. Of course, if the FDA is unconvinced about the validity of the data it can refuse to release the shipment into the commerce of the United States.
5. **Biocompatibility of Materials**
   Sunglasses and reading glasses should be made of materials that are not flammable. In addition, sunglasses and reading glasses should also

be made of materials that are non toxic, and which do not produce an allergic reaction under normal use. The ANSI Z80.3-2015 standard sets out voluntary standards for measuring the flammability of materials used in sunglasses, while criteria for measuring the biocompatibility of materials is found at International Organization for Standardization's ISO 10993.

6. **FDA Labeling Requirements**
   a) **Language and Common Name of Device**
   Because sunglasses and reading glasses are medical devices, they are subject to FDA labeling requirements. These labeling requirements apply to all medical devices, both U.S. origin and foreign origin. All medical devices must state the common name of the device in BOLD FACE type in a reasonable size font. The label must be in English, except in Puerto Rico or other U.S. Territories where English is not the primary language. In those situations, the label must be in the predominate language, such as Spanish for Puerto Rico.

   b) **Information that Must be Included**
   The label must also identify other information. It must identify the name and place of manufacture or distribution. This must be done in a conspicuous way, and must list the street, city and zip code of the principal place of business or site of production – an email address will not satisfy this requirement. If the device is made by a company other than the one identified on the label, then the label must say "Manufactured for ____" or "Distributed by ____" to denote that the company on the label did not actually manufacture the device. The label must also explain how the device is used. Sunglasses and reading glasses are exempt from providing use information but clip-ons are not.

   c) **Misbranding**
   False or misleading labels can result in the FDA determining a product to be misbranded or adulterated. For example, labels are misbranded when they contain statements that are false or misleading in any regard, are ambiguous or create a false impression. In certain circumstances silence as to a material fact can result in an allegation that a device is misbranded.

   d) **Unsubstantiated Claims of Therapeutic or Preventative Value**
   Sunglass and reading glass companies should be particularly concerned about making unsubstantiated claims of therapeutic or preventative value, as these would be considered false or misleading statements. As mentioned above, sunglasses and reading glasses are considered by the FDA to be Class 1 medical devices, requiring no FDA pre-market approval. This exemption, however, extends only to claims of use and performance previously authorized by the FDA. For example, for sunglasses the FDA has authorized that labels may state that the devices are able to block UV or reduce glare. So, labels can state things such as "lenses meet ANSI Z80.3-2015 UV blocking requirements" or "lenses block X% UVB and X% UVA," or "may reduce eye strain and/or eye fatigue due to glare." Labels can also state that the "lenses meet applicable government impact resistance requirements but are not shatterproof," and can identify whether the product is or is not intended for driving. Any claim touting a therapeutic or preventative benefit not previously authorized by the FDA would need to be submitted to the FDA via the 510K procedure for pre-market approval.

   e) **Public Service Information**
   While the Class 1 exemption limits statements as to how the sunglass or reader is to be used or will perform, labels can contain information on safety or of a public service type. Therefore, labels can contain statements such as "lenses not shatterproof or unbreakable," "not intended to function as impact protective eyewear for use in high risk impact sports or for industrial safety," or "tinted eyewear not recommended for night driving."

7. **Good Manufacturing Practices**
   Companies that manufacture sunglasses and reading glasses must meet good manufacturing practices

(GMP). The FDA describes these as "quality system regulations" impacting the design, manufacture, labeling, purchasing, storing and servicing of medical devices. Periodically the FDA audits facilities to insure compliance with GMPs. If you are audited, and found to be non-compliant, then the FDA will issue a detention order covering that facility.

8. **510(k) Pre-market Notification**
   a) **Exemption for medical devices**
   As mentioned above, sunglasses and readers are designated Class 1 medical devices by the FDA. Therefore, they are exempt from 510(k) pre-market notification as long as they are marketed in a manner consistent with the exemption.
   b) **Misbranding violates exemption**
   Any claim or advertisement that a sunglass or reader provides a therapeutic or preventative benefit that was not pre-cleared by the FDA as part of the agency's granting sunglasses and readers Class 1 status, would be considered misbranding unless first made subject to the 510(k) process.

B. U.S. CUSTOMS AND BORDER PROTECTION

1. **Customs Regulations for Sunglasses, Frames, Readers, and Lenses**
   a) **Imported Merchandise**
   U.S. Customs and Border Protection ("Customs") is the federal agency with jurisdiction over the movement of merchandise into the United States. Many sunglasses and reading glasses are imported so understanding the role Customs plays is important to those companies importing these products. Please note, however, that this document is simply an overview of the Customs laws, and that importers should consult with their Customs attorneys or other trade consultants to ensure compliance with these complex laws.
   b) **Tariff Classification**
   All merchandise imported into the United States must be classified under the Harmonized Tariff Schedule of the United States ("HTSUS"). This process results in the assignment of a ten digit tariff number to the imported product, and will identify what, if any, Customs duty is owed on the product. The tariff number and duty are presented to Customs by the importer (typically through its Customs broker) when the required paperwork is submitted to the agency at the time the merchandise is entered into the commerce of the United States.
   c) **Rates of Duty**
   As of 2016, the tariff classification assigned to sunglasses is 9004.10.0000, and the rate of duty is 2 percent ad valorem. Likewise, as of 2016, the tariff classification for reading glasses is 9004.90.0000, dutiable at 2.5 percent ad valorem.
   d) **Special Trade Programs**
   Certain countries or regions have entered into free trade agreements with the United States, with one of the benefits being the reduction or elimination of duty on most products imported into the United States that originate in those other signatory countries. The North American Free Trade Agreement ("NAFTA") is the best known of these free trade agreements. The following is a list of countries and regions that currently (as of March 2016) have signed free trade agreements with the United States where the United States is allowing duty-free treatment to sunglasses and reading glasses that qualify under the various agreements: Australia, Bahrain, Canada, Chile, Colombia, the Dominican Republic, Israel, Jordan, Mexico, Morocco, Oman, Panama, Peru, Singapore, South Korea, various Caribbean basin countries, various Andean region countries and various Central American countries. Each of these free trade agreements incorporates complicated rules of origin for determining whether or not a product is, in fact, a product of a qualifying country. Therefore, consult with your trade attorney or other customs professional to confirm that your product does qualify. Simply shipping a product from a qualifying country will not qualify it as originating in that country.

2. **Customs Valuation and Appraisement**
   a) **Taxes Imposed on Value of Merchandise**
   Because most duty rates are ad valorem (a tax imposed on the value of the merchandise), the Customs laws require that importers report an appraisable value for the merchandise. Several methods of valuing merchandise exist; however, "transaction value" is the preferred method. In a nutshell, transaction value seeks to arrive at a "free on board" ("FOB") value for the imported merchandise. As a result and depending on whether the invoice price for the imported merchandise includes things like international freight, insurance, or even duty, the appraised value that is declared to Customs might differ from the invoice price.

   b) **Complicated and Intricate Laws**
   The Customs valuation laws are much more complicated than can be described in this pamphlet. Things such as raw materials, components, packing materials, tools, dies, molds, patterns, machinery and certain engineering, blueprints or other technical data, when provided free or at a reduced cost, to the seller by or on behalf of the buyer, and when not recaptured in the invoice price, must be declared to Customs. Royalty and licensing fees, likewise, could have a Customs consequence. If present, these types of costs increase the appraisable value of the imported merchandise, resulting in more Customs duty being owed. Failure to declare these costs to Customs is a violation of the Customs laws. This can result in the imposition of civil penalties against an importer and a demand to pay back duties.

   c) **Focus of Custom Officials**
   Customs is also more likely to scrutinize the appraisable value of transactions between related parties, such as sales between a foreign parent and its U.S. subsidiary or a U.S. parent and its foreign subsidiary. Typically it is these types of transactions where elements of appraisable value go unreported, making them of greater interest to Customs.

3. **Country of Origin Marking**
   a) **What Must be Marked?**
   All merchandise imported into the United States must physically be marked with its country of origin. This marking must be conspicuous, legible, indelible and permanent so that the country of origin is conveyed to the ultimate purchaser of the product. The marking must be in English.

   b) **Defining Country of Origin**
   The country of origin is the country where the merchandise originates. It could be made in a certain country. It could be mined, raised, or grown in a particular country. It is not simply the country of export (though the country of origin and of export could be the same). In situations where the imported product is the result of manufacturing raw materials or components from multiple countries, then the country of origin of the imported product will be the country where the components or raw materials were "substantially transformed" into the imported product. A substantial transformation occurs when the components or materials undergo a change in name, character and use when manufactured into the finished product.

   c) **Implications of Customs Marking and FDA Labeling**
   Importers and manufacturers of sunglasses and reading glasses must take special care to ensure that their country of origin marking and their FDA labeling jibe with each other. As discussed above, the FDA requires that the labels on medical devices have the name and address of the manufacturer or distributor. That name and address could likely be a U.S. address if a distributor is identified. If that is the case, and if the sunglasses or reading glasses are imported, then the Customs country of origin law requires that the country of origin marking (i.e. "Made in China" etc.,) be in close proximity to the U.S. address so that the ultimate purchaser of the product can be informed as to where the product was made.

d) Exception from Marking

Many exceptions exist to the country of origin marking rule. Where an exception exists, the outermost packaging rather than the actual item need only be marked with the product's country of origin. Importers or foreign manufacturers who believe that a marking exception applies to their product should consult with their customs professional or with Customs directly before unilaterally electing to not physically mark their product but rather to mark the outer most packaging.

e) Consequences of Improper Marking

Improper country of origin marking can result in civil penalties assessed against the importer. Customs can also demand that mis-marked merchandise be redelivered to the port for marking, export or destruction. Failure to redeliver can result in the assessment of other types of damages based on a violation of the Customs bond that the importer has posted.

C. OTHER FEDERAL AGENCIES

1. Federal Trade Commission

a) What is covered by the FTC

Sunglass and reading glass companies should be mindful of using the "Made in the USA" marking. This marking designation is overseen by the U.S. Federal Trade Commission ("FTC") and applies to products made and sold in the United States. It is different than the Customs country of origin marking requirement, which applies to imported goods

b) "Made in the USA" Marking

Simply stated, merchandise cannot be sold in the United States as "Made in the USA" (or similar marking) unless the product is all or virtually all U.S. origin and is in fact made here. There is no bright line test published by the agency for what constitutes "virtually all," but any product with more than a de minimis amount of non-U.S. origin material would likely disqualify the use of this marking. So, companies manufacturing sunglasses or reading glasses in the United States using imported components or materials must be careful not to violate this marking law.

c) Conditional Markings

Conditional markings may be available for qualifying products. Depending on the facts, it may be possible to mark a product sold in the United States "made in the USA of US and imported goods" or "80% made in the USA." Companies that believe they can comply with the FTC marking law should ensure that, in fact, the product satisfies these requirements before proceeding to mark accordingly.

2. Consumer Product Safety Commission (CPSC)

a) What is Covered by the CPSC

As its name suggests, the Consumer Product Safety Commission ("CPSC") regulates certain consumer products. The various laws administered by the CPSC exclude products regulated by the FDA as medical devices, so sunglass and reading glass companies typically need not concern themselves with the CPSC. However, its laws touch a number of different areas, most notably the presence of lead in paint or surface coatings, or in paint or surface coatings found on toys or other children's products, and total lead and phthalates in toys and other children's products intended for children 12 and under.

b) Compliance Issues

The lead and phthalate laws apply to children's products, so even if sunglasses and reading glasses were not exempt because of their status as medical devices anything intended for people older than 12 would not be covered either. Accessories, such as cases or chains, when marketed and sold (or given away with the sunglass or reading glass) to children 12 and under would implicate the CPSC laws. Also, if you are marketing or selling novelty or toy sunglasses (ones that are not intended to be used as "true" sunglasses) to children 12 and under, then the CPSC laws would apply.

D. THE DEPARTMENT OF AGRICULTURE

1. What is Covered by the Lacey Amendment?

A recent amendment to a long standing Department of Agriculture law, known as the Lacey Act, could

create compliance issues for sunglass and reading glass companies that incorporate any wood or other plant material in their products.

2. **Compliance Issues**
   The amendment made it unlawful to import plant or "plant products" without an import declaration containing the scientific name of the plant, its value, quantity and country of origin. As amended, the revised law could be broadly applied to capture any number of products. In light of this, Customs and the Animal and Plant Health Inspection Service ("APHIS"), the section within Agriculture responsible for overseeing this law, have moved to limit the products actually covered by the law. Companies knowing that their products incorporate any type of plant matter should review the Lacey Act to determine whether or not the amendment applies to them.

E. STATE LAW RESTRICTIONS OF NOTE

1. **States with Restrictions on Reading Glasses**
   Currently only four states place any restrictions on the over-the-counter ("OTC") sale of reading glasses. These states are Rhode Island, New York, Massachusetts, and Minnesota. The restrictions for each state follow.
   a) In Rhode Island, the OTC sales are limited to magnifications not exceeding 3.25 diopters, and bifocals are not allowed. Rhode Island, however, does not consider reading glasses that are part plano and part power as being bifocals so those products can be sold OTC. In addition, Rhode Island has a point-of-sale or area-of-sale displays requirement, where the following language must be displayed: "These magnifiers are not intended to be a substitute for corrective lenses; only a professional eye examination can determine your eye health status and vision needs."
   b) New York limits the OTC sale of reading glasses to magnifications not exceeding 2.75 diopters. It too prohibits the OTC sale of bifocals, but allows the OTC sale of the plano/power hybrid. The point of sale language required by New York differs slightly from Rhode Island, and the following in 10 point type must be displayed: "Attention, ready-to-wear non-prescription glasses are not intended to replace prescribed corrective lenses or examinations by an eye care professional. Continuous eye check-ups are necessary to determine your eye health status and vision needs." In addition to the point of sale language requirement, New York requires that each pair of readers offered for sale in New York attach the restrictive language directly to the unit, and that the disclaimer also appear in any advertising.
   c) Minnesota's limit on magnification cannot exceed 3.25 diopters. It does not allow the OTC sale of bifocal readers, and it has not stated a position on whether or not it considers the plano/power hybrids to be bifocals. It has its own point of sale language, which must state: "If you have experienced a vision loss, the selection of these glasses should not take the place of an eye exam."
   d) In Massachusetts the restriction is simply that a point of sale disclaimer be made for OTC readers. The language required by Massachusetts is: "These magnifiers are not intended to be a substitute for corrective lenses; only a professional eye examination can determine your eye health status and vision needs."

2. **California Proposition 65**
   a) **What is California Proposition 65?**
   Proposition 65 is a California state initiative that became law in 1986 as the Safe Drinking Water and Toxic Enforcement Act of 1986. Proposition 65 enacted environmental regulations regarding toxic chemicals that importers are subject to when they sell merchandise in that State, but may be unaware of. While some of the Proposition 65 controls are intended to protect California's drinking water sources from contamination by these chemicals, others are more widely applicable and intended to allow California consumers, residents and workers to make informed choices and take

precautions about the products they purchase and are exposed to which contain potentially hazardous chemicals.

b) Who is Affected?

Any company with ten or more employees that operates within California or sells products in California must comply with the requirements of Proposition 65. Proposition 65 also applies to retail, mail order or internet sales of products in California. If you operate in California, or simply sell your products in California, then you are subject to this law.

c) What are the Implications?

Companies selling merchandise in California need to ensure that their product complies with the State of California's Proposition 65. The proposition requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm. The list is updated quarterly, (see http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html), and so companies should review it often to ensure that they are compliant.

d) Restrictions, Warnings and Labeling

If a business has products containing chemicals which are on the list, those businesses are: (1) prohibited from knowingly discharging listed chemicals into sources of drinking water; and (2) required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as labeling a consumer product, by posting signs at the workplace, or by publishing notices in a newspaper (§ 25249.11(f)). For the most part, the obligation to label is placed on the producer or packager rather than on the retail seller (except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question).

e) Exceptions

This warning is required unless you are able to demonstrate that the exposure caused by the banned substance poses no significant risk (for carcinogens, no significant risk assuming lifetime exposure, and for chemicals causing birth defects or other reproductive harm, no observable effect assuming exposure at 1000 times the level in question). This exception may be difficult to demonstrate so companies should not use it unless they have compelling proof that the levels in their products pose no risk.

3. States with Restrictions on Eyeglass Frames

a) The State of California bans the operation of a motor vehicle while wearing glasses having a temple width of one half inch or more if any part of such temple extends below the horizontal center of the lens so as to interfere with lateral vision.

4. States Requiring Device Manufacturer Registration

a) California requires that medical device manufacturers physically located within the state file for a license from the state.

b) As of March 2016, the fee for new licenses is $1,600 and the fee for the bi-annual license renewal is $2,600.

c) The licensing process requires the state to inspect the facility unless an exemption can be applied.

II. STANDARDS

A. WHAT IS A STANDARD?

A standard is an established norm or guideline for the performance or design of a product. Most standards are voluntary and arise from consensus developed by technical committees of standards developing organizations. These committees can be comprised of both private and public sector members, who function as equal participants. Often governments may adopt or reference standards as part of its regulations. The impact resistance standard (the drop ball test) is a good example of a voluntary standard that has been incorporated into the U.S. federal regulations.

B. WHY SET STANDARDS?

Standards are set to establish minimum levels of safety and performance of products providing a consensus for what elements demonstrate "quality" and "safety" for that product. The international harmonization of standards has as its goal the facilitation of trade between nations.

C. US STANDARDS ORGANIZATIONS

1. **American National Standards Institute (ANSI)**
   - a) **What is ANSI?**
     ANSI is the national standards organization that coordinates the voluntary consensus standards and conformity assessment systems for sunglasses and readers in the United States.
   - b) **What are the Standards for Sunglasses**
     The relevant standard for sunglasses is the Z80.3-2015 standard which ANSI has approved as an American National Standard. ANSI also sets standards for lenses and frames that are relevant for sunglass production and sale.
   - c) **Is there a US Standard for Readers?**
     The reading glass standard is found at Z80.31. It was promulgated in 2012.
   - d) **Regulations and Procedures**
     Standards are actively reviewed to reflect changes in technology and marketplaces. The Z80.3-2015 sunglass standard must be reviewed every 5 years. The revised standard is circulated to the entire committee as a ballot. ANSI requires 100 percent voting "yes". Any "no" votes must be resolved before the standard can be passed or re-approved, and an explanation must be stated for a "no" vote. In the event of a "no" vote, the proposal is returned to the drafting subcommittee, where the subcommittee reviews the reason stated for the no vote. Thereafter the subcommittee will report out the proposed standard again, and the entire committee will vote on it again. So, at ANSI, one vote can block the process.

2. **ASTM International**
   - a) **What is ASTM?**
     The ASTM is an association that establishes testing standards. One of the primary missions of ASTM is to identify consistent measuring procedures for testing products.
   - b) **Standards for Protective Eyewear**
     In the United States, the ASTM established the standards for sports protective eyewear. This includes things like ski goggles, motorsports goggles, and shields used in helmets
   - c) **U.S. Representative in International Standards Organization (ISO)**
     The reason ASTM represents in ISO the sunglass industry has to do with the classification of sunglasses at the international level. In the United States, sunglasses are considered a Class 1 medical device. However in Europe, sunglasses are considered "personal protective wear," a form of safety glasses. Consequently, the ISO has tapped the ASTM as the voting member of the ISO committee and to negotiate the U.S. position in the International arena.
   - d) **Regulation and Procedures**
     Votes for a standard at the ASTM are "majority rules."

D. INTERNATIONAL ORGANIZATIONS THAT REGULATE STANDARDS

1) **The International Standards Organization (ISO)**
   - a) **What is the ISO?**
     The ISO is a non-governmental organization, consisting of national standards institutes

representing 159 countries. The purpose of the ISO is to achieve industry-wide standardization for products.

b) Regulation and Procedures

Standardization within the ISO takes place through the formation of Technical Committees and subcommittees for each specific product. Then each member organization determines its national proposed standard for the product and argues its position in the committee and subcommittee. When the subcommittee has negotiated a draft proposal and the committee has agreed upon it, the proposal goes before the entire ISO membership for a vote. If accepted by at least 75 percent of the membership, that standard then becomes the official ISO international standard for the product.

c) Is there an International Sunglass or Reader Standard?

In 2013, ISO adopted sunglass standard ISO 12312 and ISO 12311. A reading glass ISO exists, ISO 16034-2002.

d) Interactions between the ISO and the World Trade Organization (WTO)

While the standards promulgated in the ISO may technically be voluntary, as is discussed, below, membership in the WTO may require members, including the United States, to accept new ISO standards or risk defending their regulations in the WTO dispute settlement system.

2. The World Trade Organization (WTO)

a) What is the WTO?

The World Trade Organization (WTO) is an international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.

b) Harmonizing National and International Standards

As part of the negotiations for the WTO, the parties, including the United States, agreed to the Agreement on Technical Barriers to Trade ("TBT"). Pursuant to the TBT, WTO Members agree to ensure that domestic technical regulations, voluntary standards, and conformity assessment procedures do not amount to unnecessary obstacles to trade. Annex 3 of the TBT provides the Code of Good Practice. By accepting the TBT, WTO Members agree that (1) central governmental standardizing bodies will comply with the Code of Good Practice and (2) measures will be taken to ensure that local governmental bodies and non-governmental bodies also comply. In situations where international standards exist or are in the process of implementation, the Code of Good Practice requires the standardizing bodies at the national level to adhere to such standards, or at a minimum use them as the basis for their own national standards.

E) OTHER NATIONAL STANDARDS

1) European Standards

The European Union has adopted the ISO sunglass standard.

2) Australian Standards

The Australian Sunglass Standard is AS 1067-2003

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