



American Optometric Association

243 N. Lindbergh Blvd. • St. Louis, MO 63141 • (314) 991-4100

FAX: (314) 991-4101

SEAL OF ACCEPTANCE PROGRAM

Devices for Low Vision

April 1, 2006



**Meets AOA Requirements for
Devices for Low Vision.**

SEAL OF ACCEPTANCE PROGRAM SCOPE AND FUNCTION

The title of this program is the American Optometric Association Seal of Acceptance Program.

Purpose

The purpose of the program is to certify that certain ophthalmic related products conform to established, recognized and accepted standards; or, when established, recognized and accepted standards do not exist or do not fully meet the requirements of the Commission on Ophthalmic Standards (the "Commission"), it is determined that a product meets specifications developed and adopted by the Commission. An impartial evaluation of products will inform consumers that the products prescribed or purchased meet minimum standards or specifications; assist practitioners in selecting products or equipment for use in their practices and permit manufacturers to represent that their products have been independently determined to meet certain standards or specifications.

This program is conducted by the American Optometric Association's Commission on Ophthalmic Standards. The categories of products to be evaluated will be selected by the Commission on Ophthalmic Standards. Any manufacturer of an ophthalmic related product may submit its product for evaluation. If the Commission on Ophthalmic Standards determines that the manufacturer has met all requirements for acceptance, including that the product meets accepted standards or specifications, the manufacturer will then be allowed to utilize the American Optometric Association's (AOA) Seal of Acceptance in its product marketing and labeling.

Definitions

Acceptance - the procedure by which it is determined that a product conforms to an established, recognized and accepted standard; or, when established, recognized and accepted standards do not exist or do not fully meet the Commission's requirements, it is determined that a product meets particular specifications developed or modified, and adopted by the Commission.

Standard - a prescribed set of conditions and requirements, established by authority or agreement, for continuous application.

Specification - a concise statement that lists requirements to be satisfied by a product or material, and that indicates, when appropriate, the procedure by which it may be determined whether the requirements are satisfied.

Mark of conformity (acceptance) - the seal of the American Optometric Association product acceptance program that is used to identify products that have been accepted.

Manufacturer - the producer of the product who is responsible for assuring conformity with all requirements of the applicable standards or specifications.

Third party testing facility - an organization not operated or controlled by the manufacturer of a product to be accepted, that possesses the necessary technical competence and instrumentation to evaluate whether the product conforms with a standard or specification.

Structure of the AOA Commission on Ophthalmic Standards

The Commission on Ophthalmic Standards is composed of seven members who are appointed by the AOA Board of Trustees. The members are appointed for three-year terms and may be reappointed to additional three-year terms. The terms of appointment are staggered so that no more than three members will be appointed or reappointed during any one year. The AOA President designates one of the members as Chair for a one-year term. The Chair may serve more than one term. Any vacancies that may occur during a term of appointment are filled by the AOA President with the advice and consent of the Board of Trustees.

The members of the Commission on Ophthalmic Standards, staff and consultants agree to sign and abide by a Code of Conduct established for the program. The Code of Conduct specifies the elements of confidentiality of information and the areas of potential conflict of interest. The Code of Conduct requires, among other things, that any member of the Commission who has a direct or indirect relationship or involvement with a company whose product or a similar product is being evaluated shall not participate in the deliberations or voting regarding the acceptance of that product.

Consultants may be appointed to the Commission by the Chairman with concurrence of the AOA Board of Trustees. Consultants' appointments vary in length depending on the needs of the program. Consultants may participate in deliberations regarding the acceptance of products but have no vote.

Commission members may participate in meetings in person or by means of communication by which all persons participating in the meeting are able to hear one another. At all meetings, a majority of the members constitutes a quorum for the transaction of business, and the act of the majority of the members participating and who are eligible to vote constitutes an act of the Commission. No business may be transacted without a quorum present. Any action to be taken at a Commission meeting may be taken without a meeting if a consent in writing, setting forth the actions so taken, shall be signed by all of the members of the Commission. Signed written consent may be provided by facsimile or by electronic signature and approval of such action is taken by a majority of members of the Commission.

Evaluation Process

The Seal of Acceptance Program may have categories for products for which there is an established, recognized or accepted standard (e.g., ANSI, ISO, ASTM). A listing of recognized and accepted standards shall be designated by the Commission on Ophthalmic Standards for use in this program. Where no recognized or accepted standard exists for a product, or where the Commission has determined that a recognized or accepted standard does not fully meet its requirements, a product may be accepted if it meets specifications developed and adopted by the Commission on Ophthalmic Standards.

The Commission will determine which product categories are eligible for acceptance, as well as determine the standards or specifications for acceptance of a particular product category. A manufacturer may apply for evaluation of a product in a particular product category only after the Commission has formally notified the public that the product category is eligible for acceptance and the standards or specifications for acceptance. Notification of the public will occur through publication in *Optometry: Journal of the American Optometric Association* or *AOA News*.

A decision to accept a product shall be made after determining that evidence of product compliance with standards or specifications has been obtained through independent testing. A product must meet all requirements of a standard or meet all specifications for evaluation to be "accepted" by the Commission. In addition, a product will not be accepted unless the manufacturer satisfies the following requirements: Claims made for products in labeling, advertising or by other means shall not be misleading, inconsistent with the meaning of the Seal, or disparaging of other useful products available for similar purposes. All products, labeling, promotional, and related material shall conform to all applicable laws and government regulations. The manufacturer must pay a licensing fee, provide the required indemnification and evidence of insurance and sign a written contract. A manufacturer may not use the Seal unless it has written authority from the Commission and the announcement of that authorization has been scheduled for publication in *Optometry: Journal of the American Optometric Association* or *AOA News*. The Commission may impose additional requirements for particular product categories.

The process by which a manufacturer applies for and receives acceptance are described in the following sections. The manufacturer may request reconsideration of the decision by the Commission not to accept a product. The procedure is described in the Section on "Reconsideration" below.

Acceptance

The following process will be followed if a product is to be evaluated and accepted against an established, recognized and accepted standard, or specifications developed by the Commission. A product can be accepted based only on independent analysis by a third party testing facility. Information provided by the manufacturer alone will not be sufficient.

1. The manufacturer submits a completed application and samples of the product, and pays the application fee.
2. The manufacturer enters into an agreement governing the application for and participation in the AOA Seal of Acceptance program.
3. An independent testing facility with which the AOA has entered into a Third Party Testing Facility Agreement evaluates randomly selected samples of the product, as directed by the Commission, and reports the results to the Commission. The evaluation fee is paid by the manufacturer.
4. The Commission evaluates the Third Party Testing Facility's testing results for the product.
5. The Commission considers whether any claims made by the manufacturer about the product are inconsistent with the meaning of the Seal or otherwise inappropriate.
6. Based on the analysis of the above information, a decision can be made regarding acceptance. If the product meets all requirements as specified by the applicable standard or specification, the product may then be "accepted" by the Commission on Ophthalmic Standards provided that the manufacturer meets the following additional requirements:
 - a. Provides evidence of general liability insurance and indemnification in accordance with the agreement governing the application and participation in the AOA Seal of Acceptance program.
 - b. Pays the licensing fee to cover use of the Seal for a three-year period of time.
 - c. Meets any other requirements that the Commission may impose for particular product categories.
7. After receiving written notification of acceptance from the Commission and the scheduling for publication of the announcement of acceptance of the product in the *AOA News* or *Optometry: Journal of the American Optometric Association*, the manufacturer may indicate that the product has been accepted by the Commission in approved promotional material and product labeling. For particular product categories, the Seal must always be accompanied by a short statement authorized by the Commission to define the specific standard or specification to which the product conforms.
8. In the event that acceptance of a product is withdrawn or suspended, all reference to the "acceptance" classification with the product must be discontinued within three months of the date of notification by the Commission. This time frame is established to allow the company time to deplete or remove products already in the distribution pipeline. If the Commission becomes aware of factors that affect public health or safety, immediate discontinuance of use of the Seal may be required.

Procedures for the Development of Specifications for the Seal of Acceptance

Specifications developed or modified under the Seal of Acceptance Program are for a product category and not for an individual or specific product. The Commission publicizes the establishment of the specifications for a particular product category after which the Commission evaluates products in that category for acceptance. All products that fall within the category must meet the specifications that have been established by the Commission in order to be accepted.

The specifications developed or modified shall include:

1. The specific characteristics or qualities of the product which will be required, and
2. The specific criteria that will establish the acceptability of the product.

The following procedures will be used in determining the product specifications to be applied for the Seal of Acceptance program. A committee of the Commission will be selected by the Chairman to draft a document of specifications for the product category to be evaluated. Specifications for a product category may be developed by the Commission on its own initiative or at the request of another source at the Commission's discretion. The Committee will develop or modify specifications utilizing the following resources as appropriate:

1. Literature searches -- review of scientific and clinical literature relating to the product category.
2. Outside consultant(s) -- consultation with individuals or groups with expertise related to the development, manufacture, testing or use of the product category.
3. Manufacturers -- discussion with various manufacturers and producers of related products regarding product development, manufacturing, testing and use.
4. Trade or professional organizations -- review of information and guidelines established by any trade or professional organization related to the product category.
5. Government -- consultation with any government agency with regulatory or administrative responsibility for the product category (e.g., FDA, Consumer Product Safety Commission, OSHA, etc.)
6. Standards Developers – review of existing standards developed by ANSI, ISO, etc.

Information gained from these sources will be used by the committee to draft initial specifications for acceptance within a product category. A tentative draft of specifications will be provided to the full Commission, consultants selected by the Commission, and interested parties for review and comment. Any further recommended modifications or changes made by the reviewers will be considered by the committee and incorporated into a final document of specifications. The final specifications must be adopted by a majority vote of the Commission. The Commission

will notify the public of the specifications for the product category through their publication in *Optometry: Journal of the American Optometric Association* or the *AOA News*, after which manufacturers may submit products in that product category for evaluation.

Mark of Conformity

The program mark of conformity (Seal of Acceptance) issued by the AOA shall be used to indicate that products or materials have been found to conform to all requirements for acceptance as designated by the AOA Commission on Ophthalmic Standards.

The information appearing with the mark shall identify:

1. The manufacturer of the product or material.
2. The product or material name, type or model number and supplementary information providing traceability.
3. The applicable standard(s) or specification(s). However, when the Commission determines this to be impractical, the applicable standard(s) or specification(s) shall be disclosed by other means, such as in product inserts or other literature accompanying the product.
4. Any additional information that the Commission determines shall be included.

The AOA shall maintain a product directory listing all companies and products authorized to use the mark of conformity. It shall also annually publish within *Optometry: Journal of the American Optometric Association* or the *AOA News* a product directory listing of all companies and products authorized to use the mark of conformity.

The mark of conformity is owned and controlled by the AOA. As permitted in the Rules for Use of the AOA Seal of Acceptance, the mark of conformity may be used in advertising publicity or promotions. The use of the mark of conformity by manufacturers shall be unambiguous and provide no basis for misinterpretation. It should clearly state what products and what specific characteristics are covered by the mark of conformity.

The mark of conformity shall be issued for a three year period. Prior to the end of three years the manufacturer may request a reissuance of use of the mark for additional three year periods. Renewal will be granted once the manufacturer has met all requirements of the program.

Rules for Use of the AOA Seal of Acceptance

The following are the rules governing the use of the Seal of Acceptance:

1. The Seal of Acceptance (“the Seal”), except as otherwise provided, may be used after acceptance of the product has been scheduled for publication in *Optometry: Journal of the American Optometric Association* or the *AOA News*.
2. Any statement authorized by the Commission to define the specific area of usefulness of a product or to indicate the scope of acceptance shall accompany the Seal wherever it appears and shall conform to the same rules pertaining to the use of the Seal.
3. In the event that the acceptance of a product is withdrawn, use of the Seal and/or an authorized statement in connection with the product must be discontinued within three months of the date of notification to the manufacturer by the Commission.
4. The Seal shall be legible and shall not be used in any manner which detracts from its dignity.
5. The Seal may appear only once in an advertisement, once on each side of the package insert, and once on each side of the package and/or product container.
6. The use of the Seal shall be unambiguous and provide no basis for misinterpretation.
7. The Seal is to be used without comment by the manufacturer on its significance unless such comment has been previously approved by the Commission.
8. The manufacturer may not transfer the right to use the Seal or permit any other entity to use the Seal, or AOA's name, abbreviation, symbols, or any other form or reference which may be interpreted to mean the American Optometric Association, or AOA Seal, or AOA's Seal of Acceptance Program, on or in connection with the same product under a different name or label.
9. After receiving written notice from AOA that a person or entity is using the AOA Seal, or AOA's name, abbreviation, or symbols, on or in connection with the same product under a different name or label in a manner not authorized by the AOA, the manufacturer shall be required to cease selling its products to such person or entity within thirty (30) days.
10. The Commission may impose special requirements on the use of the Seal for particular products.
11. Advertisements utilizing the Seal may only carry the name of the manufacturer of the product. Unless otherwise authorized by Private Label Agreement, distributors or sellers of the product other than the manufacturer cannot use the Seal in connection with their own name.

12. The Seal shall be used in accordance with the AOA Logo Standards Manual.
 - a. The Seal can be reproduced in black, white or PMS process blue only.
 - b. Use of the arial or optima typeface is recommended in printing the clarifying language required to be used with the Seal.
13. No labeling and advertising of the manufacturer's product may make use of the Seal in a manner which conveys to the public that:
 - a. The Seal has been granted in connection with any product for which the Seal has not, in fact, been granted; or
 - b. The Seal has been granted in connection with a characteristic or capability that was not the basis for the Commission's acceptance of the product.
14. Use of the Seal on products sold outside the United States and its possessions or territories is permitted with prior explicit Commission approval. (See section on international use of the Seal.)
15. Manufacturers are required to submit samples of proposed advertising or labeling for products carrying the AOA Seal prior to use.

Reconsideration

Any manufacturer whose product has failed to be accepted, or whose acceptance has been withdrawn, may request the Commission to reconsider its decision.

The reconsideration request shall be submitted in writing to the Commission on Ophthalmic Standards. The request shall contain all pertinent details and the manufacturer's reasons why the decision should be reconsidered.

The Commission shall provide a written response to a manufacturer's request for reconsideration.

Products Not Meeting Standards or Specifications

It shall be the policy of the Commission that any product that fails to meet the established standards or specifications will not be reported to the public. Information regarding the product failure will be reported only to the manufacturer of the product. The manufacturer will have the opportunity to modify the product and resubmit it for evaluation.

If in the judgment of the Commission, however, the product represents a hazard to public health and safety, then it may also report this information to an appropriate government agency, which has regulatory jurisdiction or authority for monitoring the product.

Reasons to Withdraw or Suspend Authorization to use Mark of Conformity

The Commission may withdraw or suspend the authorization of any manufacturer to use the mark of conformity at any time. Among the factors that may result in this action are:

1. Failure to comply with all rules or regulations pertaining to the governing standard or specification, or to the conduct of the program;
2. Any change in the manufacturer, or manufacturing process, of the product which the Commission feels is not consistent with its criteria for acceptance;
3. Any change in the product or newly discovered information, which the Commission feels is not consistent with its criteria for acceptance; or
4. Any misrepresentation or misuse of the mark of conformity.

Quality Control and Reporting Requirements

The manufacturer must assure the Commission that it has an ongoing quality control system. This quality control system shall be documented to permit review and evaluation by the Commission. The manufacturer shall: (1) provide the Commission the opportunity, if requested, to review its manufacturing facilities and inspect its records relating to the production of the product; (2) provide the Commission with a copy of its Quality Assurance Manual; and (3) certify to the Commission that it is in compliance with the most current version of ISO 9001, Quality management systems–Requirements.

Once a product is accepted, the manufacturer shall inform the Commission about complaints received by the manufacturer related to the product, as well as their resolution. Should the manufacturer receive any safety related complaint about a product that the Commission has accepted, the manufacturer must immediately notify the Commission in writing about such safety related complaint. Complaint related information will be analyzed by the Commission to determine what action should be taken, including requiring additional product testing or withdrawing or suspending use of the mark of conformity.

The manufacturer must also supply on an annual basis to the Commission proof of insurance with AOA listed as an additional named insured and a list of countries in which the product is sold.

Renewal of Products

The initial acceptance of a product will be for a three-year period. Prior to the end of that time, a manufacturer may request a renewal of the acceptance of their product by:

1. Providing evidence that the specifications of the product have not changed,

2. Assuring that an ongoing system of quality control is being maintained in product manufacturing,
3. Paying the renewal fee, and
4. Renewing the original agreement between the manufacturer and the AOA.

If any changes have occurred in the product, or if the standards or specifications for the product have changed since the previous acceptance, the manufacturer must demonstrate that the product continues to meet or exceed the standards or specifications. The Commission may require that an appropriate sampling of the product be retested. If so, the manufacturer must agree to pay all expenses related to the retesting of the product in addition to the renewal fee.

Agreement of Participation

Any manufacturer who submits a product for evaluation must agree to abide by the rules and requirements governing the program and sign a formal written contract.

Private Label Applicants

A manufacturer that has permission from AOA to use the Seal of Acceptance for a product does not have the right to grant any other entity permission to use the Seal for the same product under a different name or label. Any entity that acquires a product for which the Seal is being used, with the intention of renaming or relabeling the product, must file a new application with the AOA to use the Seal. This entity (the "private label applicant") does not have to submit in its application to the Commission any products for independent testing, provided that all of the following conditions are satisfied:

1. The product submitted by the private label applicant must be identical to the product that already has been awarded the Seal. The private label applicant must certify this fact to the Commission.
2. The manufacturer that already has permission to use the Seal (the "original applicant") must certify that the product it conveyed to the private label applicant is identical to the product that already has been awarded the Seal.
3. The private label applicant must submit product sample to the Commission for inspection.
4. The time period for the private label applicant's use of the Seal expires at the same time as the original applicant's.
5. The private label applicant must pay the full application fee for each product, but the licensing fee will be pro-rated (based on the fee applicable at the time of the private label applicant's Acceptance) for the reduced period for its use of the Seal.

6. The private label applicant must state the brand names under which the product will be marketed.
7. The private label applicant must sign a contract, provide the required evidence of insurance and indemnification, and comply with all other terms and conditions for its use of the Seal.

International Use of the Seal

1. The Seal may be used in a country or countries outside of the United States of America or its territories and possessions, provided that the Commission grants prior explicit permission for such use.
2. Use of the Seal requires compliance with all applicable laws in each country in which the product is sold.
3. Use of the Seal requires compliance not only with all of the requirements for domestic use of the Seal, but also with any additional conditions the Commission may require. At present these additional requirements include the naming of a contact person located within the United States who is responsible for international marketing of the product, and the naming of all the countries where the product is marketed or sold.
4. The Commission reserves the right to revoke permission for use of the Seal in any country or countries.

Third Party Testing Facilities

The Commission will contract with independent testing facilities which have been approved to carry out the necessary evaluations. A formal written contract will be signed by the testing facility. All testing facilities must agree to meet requirements as specified by the Commission. These requirements shall include:

1. The testing facility shall enter into a Third Party Testing Facility Agreement with the AOA.
2. The testing facility shall be legally identifiable and independent of any manufacturer submitting products for evaluation.
3. The testing facility shall have and follow an operational quality assurance manual, shall have and maintain appropriate records of all testing performed, and shall provide the Commission with complete reports of testing.
4. The testing facility shall maintain adequate facilities and appropriate testing equipment, shall provide appropriate calibration and maintenance of instrumentation, shall utilize appropriate sampling and test methods, and shall maintain control of the testing environment.
5. The testing facility shall retain a competent and qualified project manager, shall retain competent and qualified technical personnel, and shall have and maintain a job description for each technical position.
6. The testing facility shall provide for the confidentiality of all test results and other information.
7. The testing facility shall agree to hold the AOA and the Commission harmless against any or all losses arising out of negligent acts or omissions or willful misconduct or breach of its Third Party Testing Facility Agreement with the AOA.
8. The testing facility shall provide the Commission, upon request, the opportunity for audit or inspection of testing facilities or procedures.
9. The testing facility must be accredited by the American Association of Laboratory Accreditation or, where applicable, other accrediting organizations, and shall agree to carry out all testing in accordance with the Standards of the most current version of ISO/IEC 17025.
10. The testing facility shall agree to be in compliance with all applicable governmental laws, regulations, procedures or other requirements.

Fees

The manufacturer shall pay the following fees under the Seal of Acceptance Program that cover the costs of administration and development of the Program:

1. Application fee - a non-refundable fee will be paid at the time of application by a manufacturer for each product evaluation.
2. Evaluation fee - based on the costs for evaluation and testing of the product. The manufacturer shall pay all reasonable fees related to the evaluation and testing of the product and shall reimburse the Commission for the reasonable cost of obtaining any products for testing.
3. Licensing fee - once a product has been accepted, the manufacturer must pay a licensing fee before use of the mark of conformity will be authorized. This fee may be pro-rated for private label applicants (see section on private label applicants).
4. Renewal fee - after three years the manufacturer will have to pay a renewal fee in order to continue to use the mark of conformity for an additional three year period. This fee will be equal to the licensing fee in effect at the time of the renewal.

Application for Product Acceptance

Communications with the AOA Commission on Ophthalmic Standards shall be in writing and shall be directed to the Commission on Ophthalmic Standards, American Optometric Association, 243 N. Lindbergh Blvd., Floor 1, St. Louis, MO 63141.

An application for product acceptance must be accompanied by the following information and such other data as may be requested by the Commission:

1. Name of product and product category.
2. Name of manufacturer, address, telephone number and contact person.
3. Description of the product along with a listing of materials used in, and method of, product manufacture.
4. Listing of any patents relating to the product.
5. Information on annual production of the product, and locations where the product is manufactured.
6. Listing of countries in which the product is marketed and sold outside the United States.
7. Evidence of the product's ability to meet specifications or standards established for this product category.

8. Indication of special or proprietary information included in application.
9. A description of quality control processes routinely performed on the product, along with a copy of the manufacturer's Quality Assurance Manual.
10. Names and qualifications of key scientific personnel responsible for formulation and testing of product.
11. Names of individuals who are authorized to furnish information and represent the firm to the Commission.
12. Current advertising and promotional material for the product.

One copy of the complete application shall be provided. The application should be accompanied by one original trade package item produced for market. Samples of the product to be evaluated shall be supplied in sufficient quantity for appropriate testing, as directed by the Commission.

CONFIDENTIAL
APPLICATION FOR PRODUCT ACCEPTANCE

1. Name/Model of product _____
2. Manufacturer _____
Product Category _____
Address _____

Telephone number _____
Contact person _____
3. Please provide a description of the product along with a listing of materials used in and the method of product manufacturing.
4. Please list any patents relating to the product.
5. Please provide information on the annual production of the product and identify the location(s) where the product is manufactured.
6. Please provide randomly selected samples of the product from each location where the product is manufactured for testing by a third party testing facility.
7. Please list the country in which the product is marketed and sold.
8. Please provide a description of the quality control process routinely performed on the product, and a copy of your current Quality Assurance Manual.
9. Please indicate any special or proprietary information included in application.
10. Please provide the names and qualifications of key scientific and/or technical personnel responsible for formulation and testing of product.
11. Please provide a listing of the names of other individuals who are authorized to furnish information and represent the firm to the Commission.
12. Please provide samples of current advertising and promotional material for the product.
13. Please state whether you comply with, and will continue to comply with ISO 9001-2000, Quality management systems–Requirements.

One copy of the completed application with accompanying materials should be sent to the Commission on Ophthalmic Standards. The application should be accompanied by one original trade package item produced for market and a check for the non-refundable application fee made payable to the American Optometric Association in the amount of \$2000 for the first product plus \$750 for each additional product.

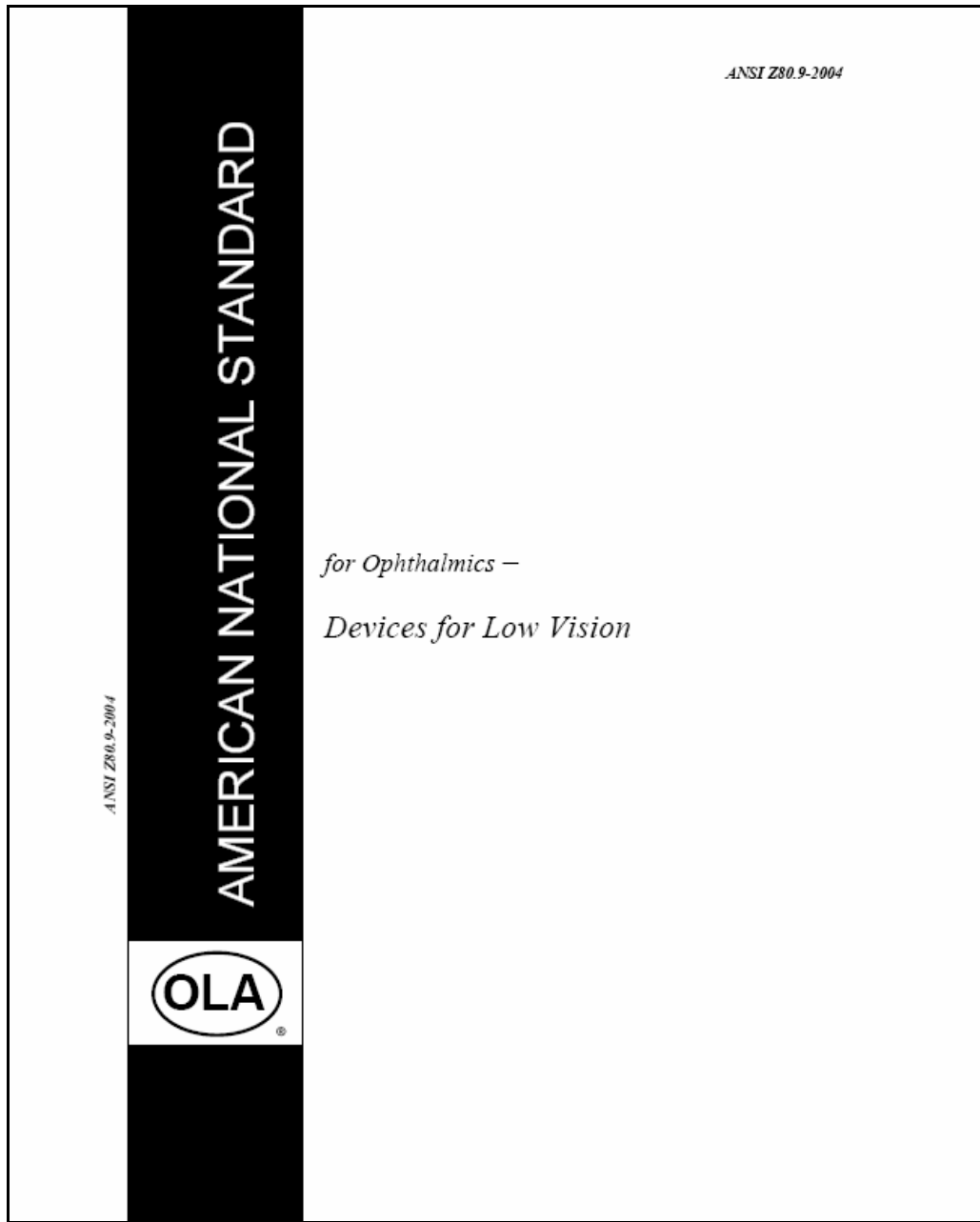
Signature of individual completing application _____

Title _____

Mail to: COMMISSION ON OPHTHALMIC STANDARDS
AMERICAN OPTOMETRIC ASSOCIATION
243 NORTH LINDBERGH BLVD., FLOOR 1
ST. LOUIS, MO 63141

AMERICAN OPTOMETRIC ASSOCIATION REQUIREMENTS FOR DEVICES FOR LOW VISION

The current ANSI Z80.9 Standard “Devices for Low Vision” specifies the minimum requirements and test procedures necessary for the AOA Seal of Acceptance in this category. All product specifications must be in conformance with the provisions of this document. Copies should be available from the American National Standards Institute e-Standards store at <http://webstore.ansi.org>.



**CLARIFYING LANGUAGE FOR USE WITH THE AOA SEAL OF ACCEPTANCE FOR
DEVICES FOR LOW VISION**

Whenever the Seal of Acceptance is used in product labeling or advertising, specific clarifying language established for that product category must also appear with the Seal. The clarifying language must appear in close proximity to the Seal of Acceptance.



**Meets AOA Requirements for
Devices for Low Vision.**