

Acceptance Program Requirements



Athletic Mouthguards



Acceptance Program Requirements

This document outlines specific category requirements. Please also refer to the General Guidelines for Participation in the ADA Seal of Acceptance Program.

Category:	Athletic Mouthguards
Purpose:	The Acceptance Program applies to over-the-counter dental products for which safety and efficacy has been established by laboratory and/or clinical evaluations where appropriate. Accordingly, the purpose of these requirements is to provide a structure upon which Athletic Mouthguards can be considered for ADA Acceptance.
Scope:	<p>These requirements apply to all athletic mouthguards available over-the-counter. For purposes of these requirements, over-the-counter athletic mouthguards are divided into the following two categories:</p> <p>Type I: This category covers over-the-counter mouthguards that are available as stock, ready-to-use products.</p> <p>Type II: This category cover mouth-formed products that are available over-the-counter. Type II athletic mouthguards are typically made from thermoplastic materials that are first heated and then inserted in the mouth and formed over the teeth, usually by biting the softened material.</p>
Notice Regarding Submission of Copyrighted Materials:	<p>To make the review of submissions to the ADA Acceptance Program as efficient as possible, the Council on Scientific Affairs provides copies of submitted materials to Council members and consultant reviewers, and also posts submitted materials to an area of the ADA's web site the access to which is restricted to Council members and staff.</p> <p>By making a submission, you are representing and warranting to the Council on Scientific Affairs and the ADA that you have obtained sufficient permission(s) from the copyright owner(s) of any copyrighted material included with your submission to allow for the publication and distribution of that material by the ADA as described above, and agree to indemnify and hold ADA harmless from any and all claims arising from such publication or distribution.</p> <p>Questions can be directed to adaseal@ada.org.</p>



1. SEAL STATEMENT

The following statement applies to products approved under the below-listed criteria:

“The ADA Council on Scientific Affairs’ Acceptance of (Product Name) is based on its finding that the product is safe and helps protect teeth from impact trauma, when used as directed.”

Format for product packaging:

- Helps protect teeth from impact trauma during sports

2. SUBMISSION DIRECTIONS

- A. Submissions are to be sent in electronic format (email) to adaseal@ada.org. Additional instructions will be provided regarding shipment of necessary samples.
- B. The submission fee is a one-time, non-refundable fee and is required before review begins. Maintenance fees are billed to the company in January of every year.
- C. The review timeline for new submissions is typically 4-6 weeks after all materials have been received. The decision to award the ADA Seal to a new product is made by the Council on Scientific Affairs. Family submissions may take anywhere from 2-4 weeks to review. Eligibility criteria for Family Submissions are outlined in the Guidelines for Participation in the ADA Seal of Acceptance Program.

Note: This is an estimated timeline. Extended review time may be required if additional information or clarification is needed from the manufacturer.

- D. When a product is classified as “Accepted” and is awarded the ADA Seal of Acceptance, the Acceptance period is five years. Manufacturers will be contacted approximately six months before the expiration of the current Acceptance period to complete the requirements for the next five-year Acceptance period.
- E. Classification of a product under the Acceptance Program is subject to the conditions stated in the Agreement Governing Use of ADA Seal of Acceptance.
- F. Guidelines for the design and conduct of clinical studies are provided in Appendix I. Manufacturers interested in seeking the ADA Seal of Acceptance are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

3. SUBMISSION MATERIALS

All submissions must include the following information based on product type and comply with the ‘General Criteria for Acceptance’ described in the Guidelines for Participation in the ADA Seal of Acceptance Program.

- A. Product Information
 - i. Name of product(s)

- ii. Name of company
- iii. FDA Documentation
 - a) FDA registration and product listing must be provided.
 - b) Evidence of FDA approval to market, if applicable (e.g., 510 (k) letter, pre-market approval, NDA/Evidence of FDA registration).
- iv. Product Claims
 - a) Products approved under these category requirements will receive the following Seal bullet claim: helps protect teeth from impact trauma during sports. Data required to substantiate efficacy towards the Seal bullet claim is explained in Section C below. ***Please provide a list of all additional safety and efficacy claims beyond the Seal bullet claim. These claims should follow the ADA Advertising Standards and must undergo review and approval by the Council on Scientific Affairs before they can be included on product packaging.*** Substantiation for any health benefit claims, outside of the Seal bullet claims, must be provided through clinical and/or laboratory data specific to the product and is not addressed in Section C below. Whether clinical or laboratory data is required depends on the nature of the claim. For any questions regarding claim substantiation, please contact the ADA Seal Program.
- v. Product Specifications
 - a) Chemical composition or components of the product and purpose of the various ingredients. To facilitate review, submitting the chemical composition, concentration, and purpose in tabular form is recommended.
 - b) Material Safety Data Sheet (MSDS) (if applicable)
 - c) Design of the product (if applicable)
- vi. Product Manufacturing
 - a) Describe or list the quality procedures for manufacturing or testing of the product which demonstrate compliance with Good Manufacturing Practices.
 - b) Certification of Good Manufacturing Practices can also be provided.
- vii. Product Instructions
 - a) Include detailed instructions for product use.
 - b) Include indications and contraindications for use, warnings, etc.
 - c) All instructions for the use of over-the-counter athletic mouthguards should be clearly defined. For Type II products, the manner in which to heat the material shall be clearly stated (for example, the length of time the product should be immersed in

water of a specified temperature), as well as the method of insertion into the oral cavity and the length of time required for forming the appliance. This recommended protocol for preparation and use of the appliance, as defined in the instructions, is the one that is to be tested in the laboratory for the purposes of the current requirements. Any substantial departures from these instructions would represent a different athletic mouthguard and would require separate evaluation.

viii. Product Labeling/Packaging

- a) All labeling/packaging should follow the ADA Advertising Standards and must be approved by the Council on Scientific Affairs before use. Companies may submit draft copy for approval. See iv. Product Claims above.

ix. Product Samples

- a) Submission requires three samples, one from three different production lots for analysis by the ADA Laboratories.

B. Safety Data

- i. Evidence must be provided that the components of the product are safe for use in the oral cavity. When appropriate, standard toxicological, mutagenic, and/or carcinogenic testing may be required. Compliance with applicable FDA standards should be provided (where appropriate).
- ii. For Type II, evidence must be provided that preparation of the product is safe when the manufacturer's instructions are followed. It must be demonstrated that the preparation of the appliance can be performed by a lay person with minimal risk of injury to teeth, tissues, orthodontic appliances, etc.
- iii. Mouthguards should be free of sharp or jagged edges.

C. Efficacy Data

- i. For Type I and Type II products, supply one copy of all available physical property data developed in laboratory studies and in accordance with ANSI/ADA Standard No. 99 Athletic Mouth Protectors and Materials, or similar documentation that might be predictive of clinical behavior. At minimum, Hardness, Tear Strength, Impact Absorption and Rebound, as well as Water Sorption measurements should meet the requirements stated in ANSI/ADA Standard No. 99. Whenever possible, Typodont models should be used during laboratory testing.

D. Supporting Literature: Copies of the most significant articles or supporting literature demonstrating safety or efficacy of the product should be provided, where applicable.

4. REFERENCES

The following references were used in the development of these requirements and can be consulted for a more detailed discussion:

- ANSI/ADA Standard No. 41 Evaluation of Biocompatibility of Medical Devices Used in Dentistry (2020)
- ANSI/ADA Standard No. 99 Athletic Mouth Protectors and Materials, 2001 (R2023)
- ADA Advertising Standards: <https://www.ada.org/publications/advertising-standards>

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