

Acceptance Program Requirements



Home-Use Tooth Bleaching Products



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:	Home-Use Tooth Bleaching Products
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 home-use tooth bleaching products can be considered for ADA Acceptance.
Scope:	These requirements apply to all home-use tooth bleaching products utilizing any bleaching ingredient and process designed for extra-coronal application which alters intrinsic tooth color in order to improve the aesthetic appearance of natural teeth. Products which remove extrinsic stain are covered under the Requirements for Tooth Stain Removal Products.
Notice Regarding Submission of Copyrighted Materials:	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.

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.

Questions can be directed to adaseal@ada.org.



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 has shown efficacy in whitening natural teeth, when used according to the manufacturer’s instructions.”

Format for product packaging:

- Helps whiten teeth

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 whiten teeth. 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 Brand 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.
- viii. Product Labeling/Packaging
 - a) All labeling/packaging should follow the ADA Brand 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.

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. Products must meet the requirements outlined in ISO 28399:2021, Dentistry – External tooth bleaching products and ANSI/ADA Standard No. 136 Products for External Tooth Bleaching 2022. Tests include an assay for the active bleaching ingredient, surface microhardness and surface erosion.
- iii. Safety must be demonstrated in two independent clinical studies. If the product contains ingredients not on the generally recognized as safe (GRAS) list, at least one six-month clinical safety study will be required. See Appendix for details regarding clinical protocol guidelines.
- iv. Safety must be demonstrated by the absence of irreversible side effects resulting from the use of the product. Documentation of non-persistent hypersensitivity, gingival health, and adverse effects during all tests in the clinical trial are required. See Appendix for details regarding clinical protocol guidelines.
- v. Safety testing certifications - UL, ETL, CSA, or other laboratory certification or approval (if applicable).

C. Efficacy Data

- i. Supply one copy of all available physical and chemical property information developed in laboratory studies or similar materials that might be predictive of clinical use/behavior.
- ii. Efficacy must be demonstrated by two, independent clinical studies assessing the ability of the product to whiten teeth, using visual and/or instrumental methods, such as the FDI or modified UPHS criteria for esthetics outcomes and/or and spectrophotometers, according to ISO/TR 28642:2016 (Dentistry — Guidance on color measurement). A detailed description of the methodologies, including validation, calibration and controls, will be required for submission to the Council for review.
- iii. The product must demonstrate a statistically significant difference when comparing the change in stain from study baseline to endpoint vs. that change for a placebo control. See Appendix for details.
- iv. For products that also contain active agents for other purposes relevant and additional ADA Acceptance Program Requirements must also be satisfied, as appropriate.

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. 136 Products for External Tooth Bleaching 2022.
- ISO 28399:2021, Dentistry – Products for External Tooth Bleaching.
- ISO/TR 28642, Dentistry – Guidance on Colour Measurement.
- ADA Brand Standards: https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada_seal_brand_standards_nov2024.pdf

Appendix

Clinical Protocol Guidelines for Home-Use Tooth Bleaching Products

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of home-use tooth bleaching products. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of the clinical studies. The information indicated below is applicable to each independent clinical study.

Study design: Clinical trials should be randomized whenever possible, with participants allocated to treatments through a randomization process. The trials can have a parallel or a crossover design. When using a crossover design, appropriate wash-out periods must be considered for the variables being tested. Studies should be blind regarding participants, examiners, and data analysts; when blinding is not possible, a justification must be provided. IRB approval is required for all studies involving human subjects. Each subject will have a complete oral cavity examination to determine eligibility for the study. The frequency of use of the product should be representative of actual use of the product in practice; and the user should be instructed in the proper use of the product but not necessarily supervised. Studies must report all treatment groups, and an attempt should be made to assess the level of compliance of the subjects in the study.

Number of studies: At least two studies should be conducted at a different site and including a separate participant pool. Studies are expected to be independent, and free from direct control from the manufacturers. Studies are expected to adhere to the CONSORT or STROBE guidelines, as appropriate, and the checklist should be completed and uploaded with the submission. The study shall be conducted for at least the length of time consistent with the directed treatment period. Measurements should be taken at baseline and immediately post treatment, and at a follow-up period at least 2 weeks later.

Sample size: A sufficient number of subjects should be enrolled in the study to ensure that appropriate statistical tests can be performed. The protocol should describe how sample size was determined, including all assumptions supporting the calculation and clearly defining the primary and secondary outcome variable(s) for which the study is being powered. A power of at least 80%, at an alpha error of 5%, is expected for variables leading to a Seal claim.

Eligibility criteria: Subjects should be representative of the population for which the product is intended. Inclusion and exclusion criteria for participant's enrollment should be clearly described and must be provided. Subjects have a full complement of anterior teeth with no obvious signs of periodontal disease or untreated dental caries and be in good physical health with no medical problems that would contraindicate participation in the clinical study. Subjects should be screened for potential participation in the study, and the screening pool should be examined for balance in terms of gender and broad age distribution. Subjects should not be taking medication which alters natural tooth color or appearance and an adequate period of cessation of medication should be considered. Subjects must refrain from the use of oral health products other than those provided, as well as any elective dentistry. Other criteria for inclusion/exclusion of subjects must be provided.

Test product and comparator: The test product should be compared with standard of care products/methods or placebo control (control group) as defined by the ADA. Clear determination is to be made about the goal of the study to show superiority, equivalence, or non-inferiority.

Clinical procedures: The phases of the study (lead-in, test, wash-out, when applicable) should be clearly described, preferable using a diagram. The instructions given to participants regarding any study-specific procedures should be clearly described. The duration of the study, and when assessments will be performed, must be clearly described. For studies involving evaluators, their number and calibration methods should be provided, as well as intra/inter examiner agreement data.

Assessments for efficacy: Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparator (control). Color and/or whiteness measurements shall be determined at each examination using an appropriate and validated measurement device. Generally, twelve anterior teeth should be evaluated. In the case a product is intended for use on a specific region, for example the six maxillary anterior teeth, the corresponding teeth should be evaluated. The lighting conditions must be carefully controlled to guarantee that full spectrum natural light is available for measurements, that other light is excluded, and that strong absorbers (such as dark colored walls or equipment) are not present. All measurements should be made under the same lighting conditions for each examinations. When the indices used allow accurate repeated measures, it is necessary to provide a measure of intra- and inter-evaluator variance. For guidance on the assessment of color competency for potential evaluators, as well as guidance for qualified evaluators, refer to ISO/TR 28642, Dentistry – Guidance on Colour Measurement.

Assessments for safety: Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator (control). Safety must be evaluated for at least the length of time consistent with the directed treatment period. All adverse effects should be reported including altered oral sensations (burning mouth, altered taste, and tooth sensitivity) for each observation period. Evidence that the product does not adversely affect oral soft tissues, oral hard tissues, or on dental restorations (e.g. composite resins, porcelain, etc.) must be provided. Subjects should be examined in the course of the study for the presence of pathologic conditions such as oral ulceration, candidiasis, or other secondary infections of the oral mucosa that may be manifestations of the proliferation of opportunistic microorganisms.

Statistical analysis: Depending on the type of study (superiority, equivalence, non-inferiority), the statistical analysis plan should be described allowing for a comparison between the test product and the comparator, for all study variables, considering the predetermined power and significance level. Acceptance is contingent upon achieving a statistically significant difference in color and/or whiteness change from baseline in comparison to that of the placebo control. Mean group scores for color and/or whiteness on all measured surfaces will be compared at baseline and when treatment is complete. If more than two groups are being evaluated, appropriate multiple comparison tests should be used. The basis for statistical sizing must be provided in the protocol. Information to be provided includes expected examiner variance, the targeted alpha and beta values, the estimated drop-out rate, and the targeted treatment differences. Where appropriate, a non-parametric test will be used to assess safety evaluation data (normal vs. abnormal).

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