

Acceptance Program Requirements



Products Used in the Management of Oral Malodor

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:	Products Used in the Management of Oral Malodor
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 products used in the management of oral malodor can be considered for ADA Acceptance.
Scope:	These requirements apply to products that are designed to manage oral malodor of non-systemic origin. Products that manage oral malodor by either active chemical agents or mechanic means will be considered. These products should be used as adjuncts to normal oral hygiene procedures. Products with therapeutic benefits that fall under the scope of other categories of the Acceptance Program must also satisfy those requirements.
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 toothbrushes 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 helping to reduce bad breath, when used as directed.”

Format for product packaging:

- Helps reduce bad breath

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 reduce bad breath. 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.
- b) NOTE: Non-fluoride products submitted under this category alone cannot include a Seal bullet claim for cavity prevention. However, if the product includes a cavity prevention claim beyond the Seal bullet claim anywhere on the packaging, evidence of efficacy and safety in the reduction of dental caries must be provided. At least one clinical trial will be required. Please refer to the Clinical Protocol Guidelines for Caries in the ADA Seal Fluoride Dentifrice Category Requirements.

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 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. Safety must be demonstrated in two, 30-day clinical studies. If the product contains ingredients not on the generally recognized as safe (GRAS) list, at least one six-month clinical safety study may be required. See Appendix for details regarding clinical protocol guidelines.
- iii. Safety testing certifications - UL, ETL, CSA, or other laboratory certification or approval (if applicable).
- iv. All submitted dentifrices must meet ANSI/ADA Standard No. 130 or ISO 11609, Dentistry - Dentifrices - Requirements, Test Methods and Marking.
- v. All submitted oral rinses must meet ANSI/ADA Standard No. 116 or ISO 16408, Dentistry – Oral Care Products – Oral rinses.

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. Product efficacy must be demonstrated in two, independent and well-designed, 30-day clinical studies utilizing an appropriate placebo control and that assess the ability of the product to reduce oral malodor. Note that products intended to demonstrate an effect in shorter periods of time (e.g. a few hours) should be evaluated during that time period, as well as at 30 days to demonstrate continued efficacy, as well as safety.
- iii. At least one clinical study must utilize an appropriate and validated organoleptic scale, such as Rosenberg or similar. Methods utilizing commercially available instrumentation, such as those employing gas chromatography, sulfide monitors, or chemical sensors, can be used for the remaining clinical study. A detailed description of such methodologies, including validation, calibration and controls, will be required for submission to the Council for review.

- iv. The product must demonstrate a statistically significant difference when comparing the change in oral malodor from baseline to a subsequent time point (and/or endpoint) vs. that change for a placebo control. See Appendix for additional details.
- v. For products that also contain active agents for other purposes, relevant and additional ADA Acceptance Program Requirements must also be satisfied, as appropriate.

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:

- Rosenberg, M. Clinical assessment of bad breath: current concepts. J. Am. Dent. Assoc. 1996;127: 475-482.
- Pratibha, P.K., Bhat, K.M., Bhat, G.S. Oral Malodor: A review of the literature. J. Dent. Hygiene. 2006;80(3); 1-9.
- S. Van den Velde, D. van Steenberghe, P. Van hee, M. Quirynen. Detection of odorous compounds in breath. J. Dent. Res. 2009; 88(3); 285-289.
- Biniecka, M., Caroli, S. Analytical methods for the quantification of volatile aromatic compounds. Trends Anal. Chem. 2011; 30(11):1756-1770.
- ANSI/ADA Standard No. 130 Dentifrices – Requirements, Test Methods and Marking 2020.
- ISO 11609:2017, Dentistry - Dentifrices - Requirements, Test Methods and Marking.
- ANSI/ADA Standard No. 116 – Oral Rinses 2020
- ISO 16408:2015, Dentistry – Oral Care Products – Oral rinses
- 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 Oral Malodor

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of oral products for the management of oral malodor. Oral malodor (bad breath) is primarily associated with oral biofilms, particularly on the tongue dorsum and periodontal niches, which generate volatile sulfur compounds. Products for the management of malodor include those that reduce volatile sulfur compounds. Manufacturers are encouraged to submit their clinical protocols to the Council prior to the start of 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 analysis; 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. The study shall be conducted for a minimum of 30 days, with measurements taken at baseline and at 30 days, with an optional intermediate period.

Number of studies: At least two studies should be conducted at different sites 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. Thirty (30) day clinical studies are necessary showing safety and efficacy of the product.

Sample size: A sufficient number of subjects should be enrolled 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: Inclusion and exclusion criteria for participant's enrollment should be clearly described. 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. Subject population should be indicative of those for whom the product is intended. All subjects should have slight to strong oral malodor two or more hours after oral activity (eating, drinking, or brushing of teeth). Systemic causes for oral malodor should be excluded by history and examination. Unless claims are being made for a specific subset, subjects with oral disease, such as advanced periodontitis, frank caries, and mucosal diseases, as well as subjects who smoke or wear oral appliances should be excluded from the study. Since routine professional cleanings may reduce oral malodor, at least one week should elapse after any prophylaxis. Subjects who do not practice daily oral care should not be included in the studies. Patients on medications that alter oral flora (e.g. antibiotics) should also be excluded. Subjects must refrain from the use of any non-study related product for symptom relief. 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 as defined by the ADA. Clear determination is to be made about the goal of the study to show superiority, equivalence or non-inferiority. Acceptance is contingent upon a product demonstrating a statistically significant difference when comparing the change in oral malodor from baseline to a subsequent time point (and/or endpoint) vs. that change for a control. For products with chemical agents, an appropriate placebo control, along with regular oral hygiene should be utilized. For products that reduce oral malodor by mechanical means, the control group should utilize regular oral hygiene.

Clinical procedures: The phases of the study (lead-in, test, wash-out, when applicable) should be clearly described, preferably 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. Subjects should be provided with products to maintain regular oral hygiene; including a manual toothbrush, a fluoride toothpaste lacking oral malodor claims, and an interdental cleaner. No other dental cleaning aids or breath freshening products, including mouthrinses, chewing gums, breath mints or breath sprays, will be permitted during the study period. On evaluation days, subjects should refrain from using products that would affect organoleptic readings (body lotions, shampoo, perfume, lipstick, etc.). Six hours prior to evaluation of oral malodor, the subjects should refrain from eating, drinking, and oral hygiene activities. For studies involving evaluators, their number and calibration methods should be provided, as well as intra/inter examiner agreement data. Odor judges used in clinical studies should be calibrated and standardized using a range of standard odorants sufficient to reflect the different patterns of nose receptors. Examples of standard odorants for this purpose would include dimethyl disulfide, indole, cadaverine, butyric acid, and trimethylamine. Examiners should be capable of replicating their own scores to a high degree. A Kappa statistic of 0.6 would indicate satisfactory calibration for the assessment of oral malodor.

Assessments for efficacy: Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparators. At least one study should include a patient-reported assessment of perceived breath odor or oral comfort. At least one clinical study must utilize an appropriate and validated organoleptic scale, such as Rosenberg or similar. Methods utilizing commercially available instrumentation, such as those employing gas chromatography, sulfide monitors, or chemical sensors, can be used for the remaining clinical study. A detailed description of such methodologies, including validation, calibration and controls, will be required for submission to the Council for review.

Assessments for safety: Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator. Evidence that the product does not adversely affect oral soft tissues, oral hard tissues, or on dental restorations (e.g. composite resins, porcelain, etc.) should be provided. For products containing antimicrobial or biofilm-active agents, evidence should be provided that use does not result in clinically meaningful mucosal irritation, altered salivary flow, or opportunistic infection. 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. Subjects should be questioned about difficulty swallowing, speech discomfort, or oral soreness. All adverse events should be reported including altered oral sensations for each observation period (e.g. burning mouth, altered taste, xerostomia, or other characteristics unique to the product).

Toxicology: Information submitted for oral rinses shall include assessments of possible toxic effects of the active agent or adverse effects of the product formulation. These should include standard toxicological profiles depending on the particular product. All products must submit data on the mutagenicity and the carcinogenicity of the product or its active agents. It is also recommended that data be provided on the effect of the product, if any, on taste sensation, staining of oral tissue, or other characteristics that may be unique to the formulation.

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. Information to be provided includes expected examiner variance, the targeted alpha and beta values, the estimated drop-out rate, and the targeted treatment differences.

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