

Acceptance Program Requirements



Toothbrushes

- **Manual**
- **Powered**
- **Specialty**

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:	Toothbrushes
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 toothbrushes can be considered for ADA Acceptance.
Scope:	These requirements apply to the design of clinical trials and other information needed to evaluate the safety and efficacy of Manual, Powered and Specialty Toothbrushes intended for the removal of dental plaque and the reduction of gingivitis.
Definitions:	<p><u>Manual Toothbrush</u>: A device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay. (21CFR872.6855)</p> <p><u>Powered Toothbrush</u>: An AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay. (21CFR872.6865)</p> <p><u>Specialty Toothbrush</u>: A Manual or Powered Toothbrush that differs from the above-definitions in function, intended use, or appearance. If it is unclear whether the product falls under the Specialty Toothbrush category, please contact the ADA Seal Program for clarification.</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 has shown efficacy in removing plaque and helping to prevent and reduce gingivitis, when used as directed."

Format for product packaging:

- Helps remove plaque
- Helps prevent and reduce gingivitis

Note: Where a toothbrush utilizes additional, external components, the Seal Statement may be modified to indicate that demonstration of safety and efficacy is limited to the toothbrush component.

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 – All Toothbrushes

- 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 claims: helps remove plaque, helps prevent and reduce gingivitis. 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.
 - b) Disqualifying claims: The Council believes that because plaque is the etiologic agent for gingivitis and other oral diseases, the only Accepted products that will be allowed to make plaque control claims will be those that can also demonstrate a significant effect against gingivitis. If a product can only demonstrate a significant plaque reduction without a concomitant significant reduction in gingivitis, it will not be eligible for Acceptance.
- v. Product Specifications
 - a) Design of the product such as dimensions and shapes of all components, different functional modes, bristle shapes under magnification, and tuft attachment methods to the base.
- 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) Intended 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 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 inclusion of 24 toothbrushes for analysis by the ADA Laboratories.

B. Safety Data: Required submission materials are listed below by product type:

i. Manual and Powered Toothbrush

- a) Physical inspection: Toothbrush bristles shall be free of sharp or jagged edges and endpoints.
- b) Material Safety Data Sheet (MSDS): Include head parts (such as bristle material, base material, tuft attachment material, etc.), body, and case (if any). Components and colorants should comply with applicable FDA standards (where appropriate).
- c) Standards-Derived Testing: Test data should be generated based on the following standards for Manual or Powered Toothbrushes:
 - ANSI/ADA Standard No.119 for Manual Toothbrushes – 2023
 - ANSI/ADA Standard No.120 Physical properties of Powered Toothbrushes- 2022

The 'Test report' section of the applicable standards provides a comprehensive list of the required information that must be included in all test reports.

As per the standards, complete datasets demonstrating compliance with the following are required for both Manual and Powered Toothbrushes:

1. *Tuft Retention*
2. *Mechanical Strength*
3. *Chemical Challenge*
4. *Bristle Stiffness*:
 - All toothbrushes are required to have a bristle stiffness value less than or equal to 6 N/cm² when following the methods described in ANSI/ADA Standard No. 119 Annexes A and B, using the total tuft hole area only in Annex B (not tufted area for stiffness determinations).
 - *Exceptions*: The vertical load for small (e.g., children's) or very soft Manual or Powered Toothbrushes may be reduced to 2.5 N if the bristles collapse under the 5 N

vertical force required in the standard. Full calculations of the stiffness of the toothbrush must be submitted in lieu of measured stiffness. If the measured stiffness is found to be greater than 6 N/cm², a 90-day clinical study will be required to demonstrate safety (see Appendix I).

- d) Electrical Safety: Safety testing certifications such as Underwriters Laboratories, Inc (UL), ETL, CSA, or other laboratory certification or approval must be provided. This requirement may be waived for products operating from non-rechargeable batteries of low voltage.

ii. Specialty Toothbrush

- a) Physical inspection: Toothbrush bristles shall be free of sharp or jagged edges and endpoints.
- b) Material Safety Data Sheet (MSDS): Include head parts (such as bristle material, base material, tuft attachment material, etc.), body, and case (if any). Components and colorants should comply with applicable FDA standards (where appropriate).
- c) Standards-Derived Testing: Specialty brushes should conform to the standard testing guidelines outlined above. If the product scope falls outside the standards listed above for Manual or Power Toothbrushes, adherence to applicable benchmarks outlined in relevant ANSI/ADA or ISO standards will be considered. Demonstration of product safety via post market surveillance and relevant clinical trial is required and will be considered alongside or in lieu of benchmark data.
- d) Electrical Safety: Safety testing certifications such as Underwriters Laboratories, Inc (UL), ETL, CSA, or other laboratory certification or approval must be provided.
 - This requirement may be waived for products operating from non-rechargeable batteries of low voltage.

C. Efficacy Data: Required submission materials are listed below by product type:

- i. **Manual and Powered Toothbrushes**: If the product is similar to an ADA accepted product, then clinical efficacy studies will not be required if:
 - a) brush meets the requirements described for safety, and
 - b) does not differ significantly in design or function from previously Accepted toothbrushes. Evidence of similarity with the ADA-Accepted product must be submitted for consideration.
- ii. **Specialty Toothbrushes**: Based on the design, functionality and available scientific evidence, product efficacy must be demonstrated via submission of one of the following options:
 - a) Two independent and registered clinical studies of at least 30 days.
 - b) One independent and registered clinical study of at least 30 days with post market surveillance data.

*Clinical studies must reflect the intended, real-world use of the toothbrush and demonstrate a statistically significant reduction in plaque and gingivitis. **Clinical studies must adhere to Guidelines provided in Appendix I.***

Note: Upon review of the product, the Council on Scientific Affairs may advise additional requirements for Acceptance where concerns for safety/efficacy remain.

- 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. 119- 2023: Manual toothbrushes
- ANSI/ADA Standard No. 120-2022: Dentistry – Physical properties of powered toothbrushes
- ADA Advertising Standards: <https://www.ada.org/publications/advertising-standards>

Appendix I

Clinical Protocol Guidelines for Toothbrushes

The following clinical protocol is suggested for the design and conduct of clinical studies using Manual, Powered, or Specialty Toothbrushes to provide evidence of safety and effectiveness in reducing gingivitis and removing plaque. Other well-designed clinical study designs could also be acceptable. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

Sample Size: At least 30 patients for each product will be available for examination at the end of the study. Each subject will have a complete oral cavity examination to determine eligibility for the study. In general, subjects should be adults of normal health with mouths free from major hard or soft tissue lesions. Entry criteria should include patients with mild to moderate gingivitis and exclude those with aggressive, necrotizing, or other uncommon periodontal disease states. The control toothbrush to be used in the study must be ADA Accepted.

Study Duration: The study will be conducted for at least a 30-day period to assess efficacy. However, for toothbrushes which do not meet the bristle stiffness requirements, the safety assessments should be continued for a total of 90 days. For efficacy studies, measurements will be taken at baseline (prior to the study), 15 days (optional) and 30 days. For determination of safety, baseline, 15-day, 30-day, and 90-day measurements will be taken.

Clinical Procedure: All clinical examinations will be performed by an investigator who has no knowledge of the oral hygiene devices used by the subjects. It is desirable to provide a measure of intra- and inter-evaluator variance. 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.

Between the baseline and 30 days (90 days, if necessary) examination, each subject will be instructed to brush his/her teeth daily, using the test or control toothbrush and an assigned ADA Accepted fluoride dentifrice. No other dental cleaning aids such as dental floss will be permitted during the study period. An attempt should be made to assess the level of compliance of the subjects in the study. Examination of toothbrush condition at the conclusion of the study is one method of attempting this assessment.

Safety Assessments: Safety assessments will be made at each measurement period on oral soft and hard tissues and on restorations. Areas to be examined will be the tongue, hard and soft palate, gingivae, mucobuccal folds, the inner surface of the cheeks, and sublingual space areas. Any effects on hard tissue and/or dental restorations should be reported, and analyzed (normal vs abnormal) by an acceptable non-parametric test. In particular, the cervical root area will be carefully examined.

Gingivitis Assessments: The comprehensive Löe & Silness gingival index which incorporates both bleeding and visual appearance can be used. Alternatively, the visually-based Modified Gingival Index can be used along with an index of gingival bleeding, such as the Eastman Interdental Bleeding Index. Full mouth evaluations including 6 sites per tooth (mesio-buccal, buccal, disto-buccal and mesio-lingual, lingual, disto-lingual) on a minimum of 20 teeth should be performed.

Plaque Assessments: Plaque will be scored before and after brushing at each examination using the Turesky modified Quigley-Hein Index, or another appropriate and validated index. Full mouth plaque evaluations should be performed.

Statistical Analysis: Within each group, means and standard deviations for all clinical measurements and assessments for the entire dentition of each will be made. Groups will be compared at baseline, 15 days, 30 days, and, if appropriate, at 90 days with either a parametric or non-parametric test for matched pairs. If more than two groups are being evaluated, appropriate multiple comparison tests should be used. Repeated measures multivariate analysis of variances (ANOVA) can be used to test for time and device dependent differences for all clinical assessments between subject groups. A pooled average of at least 10% (using the Modified Gingival Index) or 15% (using the Löe and Silness Gingival Index) compared to baseline is required to demonstrate a reduction in gingivitis; the confidence interval must be provided. Plaque measurements shall demonstrate a

statistically significantly reduction from the baseline measurement. Furthermore, the reduction in whole mouth gingivitis and plaque in the test toothbrush group shall not be significantly less than reductions in whole mouth gingivitis and plaque for the control toothbrush group.

Where appropriate, a non-parametric test will be used to assess the 90-day safety evaluation data (normal vs. abnormal).

Independent Studies: Clinical studies of similar design (double blind, where possible), conducted at different sites (where at least one site is not under direct control of the sponsoring company), by different investigators and using different study subjects and an appropriate control. "Direct control" does not prohibit monitoring of the investigation by the company for legitimate business purposes, as long as such monitoring does not interfere with the scientific autonomy of the investigators.

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