Acceptance Program Requirements

Denture Adherents

ADA American Dental Association®
Council on Scientific Affairs

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:	Denture Adherents
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 denture adherents can be considered for ADA Acceptance.
Scope:	These requirements apply to products designed to improve retention of dentures as a temporary measure.
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 helping to temporarily provide increased retention of dentures, when used as directed."

Format for product packaging:

- Helps temporarily increase retention

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 temporarily increase retention. 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.

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. In cases where agents that do not appear on the GRAS list have been introduced into a denture adherent, one six-month clinical study may be required, which includes examinations of oral soft tissues, toxicological studies, and microbiological profiles that should demonstrate that pathogenic or opportunistic microorganisms do not develop over the course of the study (see Appendix). In products with agents with an established record of safe use in the oral cavity, clinical testing may not be required, but the manufacturer should provide supporting data and rationale for its use in the submitted product.

iii. For products containing zinc, the package must be clearly labeled indicating its presence. Maximum safe usage quantities and frequency must be defined in easily understood terms or visuals.

iv. All submitted denture adherents must meet ANSI/ADA Standard No. 135 Denture Adhesives. Tests include biocompatibility, pH value, microbiology, stability, as well as washability and adhesion strength.

v. Laboratory tests should be submitted to demonstrate that the denture adherent will not adversely affect prostheses and their component materials under conditions of actual use (e.g. using ASTM D543-21 Standard Practices for Evaluating the plastics, and appropriate tests to show no etching, pitting, or localized corrosion of metal components).

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. Clinical studies are not required for products with well-known ingredients and for which compliance with ANSI/ADA Standard No. 135 Denture Adherents or ISO 10873:2010 Dentistry – Denture Adhesives is provided. For all other products, efficacy (and safety) must be demonstrated in two independent 30 day clinical studies demonstrating the effectiveness of the denture adherent in providing an improved performance in biting force and retention. At minimum, single-use measurements should be provided. Comparison should be made in each subject with and without the denture adherent. Additional guidelines are presented in the Appendix.

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. 135 Denture Adhesives, 2015
- ANSI/ADA Standard No. 41 Evaluation of Biocompatibility of Medical Devices Used in Dentistry, 2020
- ASTM D543-21 Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents
- ADA Advertising Standards: https://www.ada.org/publications/advertising-standards

Appendix
Clinical Protocol Guidelines for Denture Adherents

The following guidelines are for the design and conduct of clinical studies for the evaluation of the safety and efficacy of denture adherent 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.

Sample Size
A sufficient number of subjects should be enrolled in the study to ensure that appropriate statistical tests can be performed. The Council recommends that a minimum of 30 subjects per group complete the study.

Subject Selection
All subjects should 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. Subject population should be indicative of those for whom the product is intended. Specifically, patients with poor to fair fitting complete maxillary and/or mandibular dentures should be included. Subjects must refrain from the use of any non-study related denture adherent. Other criteria for inclusion/exclusion of subjects must be provided.

Study Duration
The Council recommends that two 30 day clinical studies are necessary showing safety and efficacy of the product. For products containing non-GRAS ingredients, a 6 month study showing safety may be required.

Study Design
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 groups and an attempt should be made to assess the level of compliance of the subjects in the study. The study should use a previously ADA-accepted or FDA-approved zinc-free (if applicable) denture adhesive as a positive control.

Safety Assessments
Safety must be evaluated and acceptance is contingent upon demonstrating the absence of irreversible side effects resulting from the use of the product.

Adverse Events
All adverse events should be reported including altered oral sensations for each observation period (e.g. burning mouth or altered taste).

Effect on oral tissues
Evidence that the product does not adversely affect oral soft issues should 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.

Efficacy Assessments

Statistical Analysis

Acceptance is contingent upon achieving an equivalent or significantly improved performance in biting force and retention of the denture adherent upon a single use. Comparison should be made in each subject with and without the denture adherent in comparison to a positive control. Appropriate statistical methods should be used.