

Acceptance Program Guidelines

Denture Adherents

ADA American
Dental
Association®
Council on
Scientific Affairs

2008

Council on Scientific Affairs **Denture
Adherents**

Scope:

These guidelines apply to products designed to improve the retention of dentures as a temporary measure. A dentist should be consulted as soon as possible so that the ill-fitting denture can be adjusted or replaced.

I. SUBMISSION DIRECTIONS

1. General Information

A Submissions are to be sent to the Council Office:

**Director, Product Evaluations
Council on Scientific Affairs
American Dental Association
211 East Chicago Avenue
Chicago, Illinois 60611 - 2678**

B Submissions are to be sent in triplicate, along with one single-sided copy for duplicating purposes. Three samples of each product from different lots shall be provided. Market samples are preferred. If possible the submission should

be

less than 200 pages exclusive of appendices.

C A manufacturer is advised that the review process is complex. Typically, notification of Council action may be expected

90 to 150 days from the receipt of a complete submission by the Council. More time may be required if additional information or clarification is needed from the manufacturer.

D When a product is classified as "Accepted" the classification is for 3 years. Renewal of the classification will be considered by the Council upon request by the manufacturer.

E Companies with Accepted products are subject to the conditions stated in the Agreement Governing Use of ADA Seal Of Acceptance.

2. Arrangement of a Submission

A The submission is to be divided into sections and arranged in order as indicated in part II. Sections to be identified by tabs are designated by *.

II. INFORMATION TO BE SUBMITTED

1. Cover Page

A Name of company

B Product name

*2. Table of Contents

*3. Company Information

A Name of company (to be used in official list of Accepted Products)

B Address (to be used in listing)

C Phone Number (to be used in listing)

D Fax Number

E Names of owners, officers and other individuals authorized to furnish information to the Council and represent the firm in dealing with the Council. (Foreign manufacturers must have an office or branch located in the United States and the product must be available for purchase in the United States).

F Names and qualifications of scientific personnel responsible for formulation and testing of the product.

*4. Summary of submission

Comprehensive summary of the information submitted on safety and effectiveness of the denture adherent.

*5. Product Information

A Name of product (to be used in listing).

B Composition of the product and the purpose of the various ingredients.

C Claims of efficacy and safety.

- (i) Claims for the device in labeling and in advertising to the public shall be limited to those related to improve denture retention as a temporary measure. The advertising shall avoid disparagement of other products.
- (ii) Please furnish detailed information concerning any extension of claims for actions or uses beyond those currently recognized by the Council as specified above.

If the claims for the submitted product exceed those claims specified above, e.g. denture retention, it will be necessary to provide adequate evidence of the claimed usefulness of the product. This evidence may be in the

form of published reports or unpublished information obtained from appropriate scientific studies employing laboratory, animal and clinical observations.

Evidence should be adequate in both quantity and quality to permit sound conclusions. This requirement is especially important since most clinical studies involve subjective interpretations on the part of both the observer and the patient. Insuring that the data are adequate in quantity usually requires not only that individual studies include sufficient numbers of clinical cases for observation, but also that studies be provided by at least two independent groups.

D Patent title(s) and patent number(s) relating to the product.

E Labeling

F Packaging

G Promotional materials

H Detailed instructions for use.

***6. Quality Control Procedures for the manufacturing of the product**

***7. Laboratory and safety data**

A Studies shall be submitted demonstrating that the integrity of the denture is not affected by the denture adherent.

B Denture adherents shall be assessed for biocompatibility (animal studies are acceptable) and that no hazard is to be expected when used according to the manufacturer's instructions.

***8. Efficacy data - clinical data to show effectiveness**

Clinical data should be provided from at least one 14 day study demonstrating the effectiveness of the denture adherent in providing:

A Increased biting force.

B Increased retention.

Studies should be conducted on patients with poor to fair fitting complete maxillary and mandibular dentures. A suitable control group should be included. The sample size should be of sufficient power ($\beta = 0.80$) at a 95% confidence level. Proper scientific protocols must be followed for all studies. When possible, randomized clinical trials are recommended. Additional information concerning clinical trials and clinical trial reporting can be obtained from the Councils Guidelines for Clinical Trial Protocols.¹ Manufacturers are invited to submit protocols for review before implementing a study.

***9. Comprehensive bibliography concerning the product**

¹ ADA Council on Scientific Affairs. Acceptance Program Guidelines: Clinical Trial Protocols. Chicago: American Dental Association, 2007.

***10. Appendices**

Evaluation forms, detailed description of test evaluation methods and any other defined areas should be included.

III. STATEMENT TO BE USED FOR PRODUCTS CLASSIFIED UNDER THESE GUIDELINES INCLUDING QUALIFIERS:

“The ADA Council on Scientific Affairs’ Acceptance of (product name) is based on its finding that the product is effective as a temporary measure and may provide increased retention of complete dentures, when used as directed. Ill fitting dentures may impair your health - consult your dentist as soon as possible.”

ADA American Dental Association®

America's leading advocate for oral health

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