Acceptance Program Requirements

Sugar-free Chewing Gums to Help Prevent Cavities

ADA American Dental Association®
Council on Scientific Affairs

ADA Accepted
American Dental Association

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:	Sugar-free Chewing Gums to Help Prevent Cavities
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 sugar-free chewing gum used to help prevent cavities can be considered for ADA Acceptance.
Scope:	These requirements apply to sugar-free gums without active/therapeutic anticaries agents that help prevent cavities by stimulation of saliva through the act of chewing, as well as sugar-free chewing gums with active/therapeutic agents that are intended to provide an additional anticaries benefit.
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:

Sugar-free Gums Without Active Anticaries Agents:
"The ADA Council on Scientific Affairs' Acceptance of (Product Name) is based on its finding that the product is safe and that the physical action of chewing (product name) for 20 minutes after eating, stimulates saliva flow, which helps to prevent cavities by reducing acids and making teeth more resistant to decay."

Sugar-free Gums that Contain Active/Therapeutic Agents for the Reduction of Cavities:
"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 (the rest of this statement will highlight the additional benefit provided over salivary stimulation alone)."

Format for product packaging:

- Helps prevent cavities when chewed for 20 minutes after eating

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 prevents cavities when chewed for 20 minutes after eating. 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.

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 new agents that do not appear on the Generally Recognized As Safe list have been introduced, clinical studies must be submitted which include examinations of oral soft and hard tissues and restorations, toxicological studies, and microbiological profiles that should demonstrate that pathogenic or opportunistic microorganisms do not develop over the course of the study.

iii. For products that contain active/therapeutic agents, information must be provided regarding possible toxic effects of the active product and its formulation. In most cases, standard toxicological profiles are sufficient. In addition, evidence of the effects on oral flora should be provided from at least one clinical study. Oral flora should be monitored in subjects during the study for the development of opportunistic and pathogenic organisms. Evidence shall be provided that oral flora has not been adversely affected.

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. Required efficacy data depends on whether or not a sugar-free gum contains an active/therapeutic agent intended to help reduce cavities. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies.

ii. **Sugar-free Chewing Gums Without Active Anticaries Agents**

a) Clinical caries trials will not be necessary for sugar-free chewing gums without active/therapeutic anticaries agents. Instead, an in vivo salivary flow rate test is required, in which the chewing gum being submitted is compared to the ADA Accepted, clinically tested sugar-free gum as a control. The control product is available for testing purposes from the American Dental Association, or

companies may manufacture the sugar-free gum using Appendix I for stick or slab formulations.

b) Salivary flow rate tests must show an equivalent or a statistically significant improved performance when compared to the control (see Appendix II). The testing will not be required for flavor changes or minor formulation adjustments that correspond to the flavor changes of sugar-free gums that were previously Accepted and tested. However, based on the form and composition of the sugar-free chewing gum, the Council may require additional tests (see Appendix II). Manufacturers are encouraged to review chewing gum formulations with the Council for guidance

iii. Sugar-free Chewing Gums that Contain Active/Therapeutic Agents for the Reduction of Cavities

a) If a company wishes to make an anticaries claim for its sugar-free gum with one or more active/therapeutic anticaries agents, the Council requires at least two clinical caries studies showing that the gum provides statistically significantly better caries reduction than the ADA Accepted, clinically tested standard sugar-free gum, when used in the same clinical study. The ADA does not specify the study design, and it is up to the company to ensure that it is scientifically sound.

b) If a company wishes to make efficacy claims for other effects of the active/therapeutic agent (e.g. plaque pH reduction, enhancing remineralization, decreasing demineralization, reducing cariogenic plaque bacteria), then at least one clinical study demonstrating statistically significantly better performance in the selected area compared to the ADA Accepted, clinically tested standard sugar-free gum, when used in the same clinical study, must be submitted. The ADA does not specify the study design, and it is up to the company to ensure that it is scientifically sound.

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:

- Aguirre-Zero O, Zero DT, Proskin HM. Effect of chewing Xylitol chewing gum on salivary flow rate and the acidogenic potential of dental plaque. Caries Res. 1993; 27:55-59.
- Dawes C, Macpherson LM. Effects of nine different chewing-gums and lozenges on salivary flow rate and pH. Caries Res. 1992; 26:176-82.
- Jenkins GN, Edgar WM. The effect of daily gum-chewing on salivary flow rates in man. J. Dent. Res. 1989; 68:786-790.
- Jensen ME, Wefel JS. Human plaque pH responses to meals and the effects of chewing gum. Br. Dent. J. 1989; 167:204-208.
- Manning RH, Edgar WM. pH changes in plaque after eating snacks and meals, and their modification by chewing sugared- or sugar-free gum. Br. Dent. J 1993; 174:241-244.

- Park KK, Schemehorn BR, Bolton JW, Stookey GK. The impact of chewing sugarless gum on the acidogenicity of fast-food meals. Am. J. Dent 1990; 3:231-235.
- Manning RH, Edgar WM, Agalamanyi EA. Effects of chewing gums sweetened with sorbitol or a sorbitol/xylitol mixture on the remineralization of human enamel lesions in situ. Caries Res. 1992; 26:104-109.
- Leach SA, Lee GTR, Edgar WM. Remineralization of artificial caries-like lesions in human enamel in situ by chewing sorbitol gum. J. Dent. Res. 1989; 68:1064-1068.
- Creanor SL, Strang R, Gilmour WH, Foye RH, Brown J, Geddes DAM, Hall AF. The effect of chewing gum use on in situ enamel lesion remineralization. J. Dent. Res. 1992; 71:1895-1900.
- WHO. Diet, nutrition and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation. (WHO technical report series; 916). Geneva: World Health Organization; 2003.
- Title 21, Food and Drugs. U.S. Food and Drug Administration, Department of Health and Human Services. Electronic Code of Federal Regulations. Available from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101#101.60 (Accessed April 2025)
- FDA. Aspartame and Other Sweeteners in Food. U.S. Food and Drug Administration. Available from: https://www.fda.gov/food/food-additives-petitions/aspartame-and-other-sweeteners-food (Accessed April 2025)
- Ingredients technology - ICGA. International Chewing Gum Association. Available from: https://www.gumassociation.org/index.cfm/science-technology/ingredients-technology/ (Accessed April 2025)
- ADA Advertising Standards: https://www.ada.org/publications/advertising-standards

Appendix I
Standard Sugar-free Chewing Gum Formulations

ADA Sugar-free Stick Gum Formulation	
Ingredients	%
Gum Base	28.50
Sorbitol	50.10
Malitol Syrup	12.00
Glycerin	4.70
Mannitol	2.00
Peppermint flavor	1.00
Peppermint Oil	1.00
Aspartame	0.40
Acesulfame-K	0.10
Soy lecithin	0.20

ADA Sugar-free Slab Formulation	
Ingredients	%
Gum Base	30.00
Sorbitol	46.00
Xylitol	10.00
Mannitol	6.00
Maltitol	3.00
Texturizer	2.20
Sweetener	0.70
Flavor	2.10

Appendix II
Clinical Protocol Guidelines for
Sugar-free Chewing Gums Without Active Anticaries Agents

Suggested Test Protocols

The following are examples of protocols that can be used for the evaluation of sugar-free chewing gums without active anticaries agents. Other study designs will be considered if an adequate rationale is presented.

Sample Size and Design

For each of the tests, all participants should be ≥ 18 years of age and in good general health with at least 20 natural teeth and 8 natural posterior teeth (excluding molars) and normal salivary flow rates (≥ 0.4 ml/min), as determined from an unstimulated salivary flow determination. No appliances or dentures should be worn by the subjects and no medications should be taken during the study, especially those that may interfere with salivary flow. Individuals with allergies to chewing gum, history of phenylketonuria (PKU), gross untreated caries, advanced periodontitis, and temporomandibular joint disorders should be excluded. Subjects must also not be pregnant or nursing, or have participated in any other clinical study within one month of study entry or who will concomitantly participate in such a study.

Clinical Examination

In vivo salivary flow rate: A modification of the method of Dawes and Macpherson (1992) is recommended. At least 15 subjects should participate in the study. Subjects should refrain from eating for a least one hour prior to testing (preferably testing will be done early in the morning before eating that day). Subjects should use both the clinically tested gum and the submitted gum with testing conducted at approximately the same time each day. There should be at least a 48 hour washout period between each test.

Subjects will be given a chewing gum at random and instructed not to spit it out until the conclusion of the collection of saliva. They will be instructed to swallow to remove any saliva present, then to place the gum in their mouth and chew at their normal pace, frequency, and force without talking. Subjects will be instructed to expectorate as needed into a funnel inserted into a 50 mL test tube. The sample of stimulated saliva from gum chewing should be obtained after 20 minutes. Tubes will be weighed prior to and following collection, the tare weight will be subtracted from the post-collection weight, and the 20 minute flow rate will be calculated using the conversion of 1.0 gm =1.0 mL. Values should be expressed as mL per minute.

The procedure will be repeated until each of the subjects has both the test and control chewing gums. Subjects should then be surveyed regarding whether they would normally chew the submitted gum for at least 20 minutes if unsupervised.

Demographic and baseline salivary flow information for the study population as well as descriptive statistics will be presented. Salivary flow rate (ml/min) for the 2 treatments will be statistically analyzed using a mixed model method suitable for a cross-over design. The model will include a random effect for subject and fixed effects for study period and treatment. For subjects assigned to the same treatment sequence, the model will include sequence and subject within a sequence term. The submitted gum will be tested against the clinically tested gum using the following null hypothesis, H_0: There is no difference in salivary stimulation between the two gums during a 20 minute chew. The H_0 will be tested at the 5% significance level (two sided). All the comparisons to the control (clinically tested) gum will be performed using Dunnett's adjustment.

In vivo rate of return of plaque pH following a cariogenic snack: A modification of the method of Aguirre-Zero, et.al (1993) is recommended. At least 15 subjects should participate in the study. A double-blind, crossover design should be used. Two days before the test, the subjects should refrain from all oral hygiene procedures to permit plaque growth for pH determination. Plaque pH measurements should be made in the morning with subjects refraining from all food or drink for at least 6 hours. After the baseline plaque pH has been measured, the subjects should rinse with a 10% sucrose solution for one minute and then the submitted or clinically tested gum should be chewed with plaque pH monitored at 5, 10, 20, 30 and 40 minutes following the sucrose rinse.

In situ remineralization: While the method of Leach, Lee and Edgar (1989) is recommended, a number of different in situ remineralization models will be considered. The in situ model shall, however, include the formation of a dental biofilm and diet-induced acid challenges to the partially demineralized enamel specimens which remain in the mouth for the duration of the study so that remineralization is occurring under clinically relevant conditions. At least 15 subjects should participate in the study, which should involve a double-blind, crossover design with a one week washout in between. Chewing gum periods should last for two or three weeks depending on the type of in situ model. Gums should be chewed at least several times per day, each time for 20 minutes.