

Acceptance Program Requirements



Sugar-free Chewing Gums to Help Prevent Cavities



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 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.
- 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.

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 a clinically tested gum, preferably approved for the ADA Seal, as a control. 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 clinically tested standard sugar-free gum control, 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 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 Brand Standards: https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada_seal_brand_standards_nov2024.pdf

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

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of sugar-free chewing gums without active anticaries agents. Other study designs will be considered if an adequate rationale is presented. Manufacturers are encouraged to submit their clinical protocols to the Council for review prior to the start of clinical studies. The information indicated below is applicable to each independent clinical study.

Study design: Studies 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 analysts; when blinding is not possible, a justification must be provided. IRB approval is required for all studies involving human subjects.

Three types of studies are described here assessing different parameters associated with the potential of sugar-free gums to help prevent cavities. Please note that salivary flow rate tests are required for products applying for the Seal.

1. **In vivo salivary flow rate:** This test will determine stimulated salivary flow rate over 20 min of chewing of the test gum and an appropriate chewing gum control.
2. **In vivo rate of return of plaque pH following a cariogenic snack:** This test will determine the dental biofilm pH for up to 40 min after a 10% sucrose solution rinse is performed, followed by chewing of the test and comparator gum.
3. **In situ remineralization:** In this study, previously demineralized enamel slabs will be exposed to the mouth of participants for 2 to 3 weeks, during which test and control gums will be chewed several times/day, each time for 20 min.

Number of studies: One study is accepted for the assessment of flow rate, plaque pH and remineralization. (Note that for gums containing active/therapeutic agents for the reduction of cavities, two clinical studies are required). Studies are expected to adhere to the CONSORT or other appropriate guidelines, and the checklist should be completed and uploaded with the submission.

Sample size: The protocol should describe how sample size was determined, including all assumptions supporting the calculation and clearly defining the primary and any 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. Note that previous versions of this guideline recommended a minimum sample size of 15 participants for all three different types of studies described here, which can serve as a reference for the planning of new studies. Still, sample size calculation is required in the protocol.

Eligibility criteria: Trial participants should be representative of the population for which the product is intended. Inclusion and exclusion criteria for participant's enrollment should be clearly described.

Test product and comparator: The test product should be compared with a clinically tested gum, preferably approved for the ADA Seal for this category. Clear determination is to be made about the goal of the study to show superiority, equivalence or non-inferiority. Note that for the salivary flow rate test, products must show an equivalent or a statistically significant improved performance when compared to the control.

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. For studies involving evaluators, their number and calibration methods should be provided, as well as intra/inter examiner agreement data.

1. **In vivo salivary flow rate:** A modification of the method of Dawes and Macpherson (1992) is recommended. Participants should refrain from eating for a least one hour prior to testing; preferably testing should be done early in the morning before eating that day and conducted for all groups at approximately the same time of the day. A 48-h washout period is recommended between the test of each group. Participants 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. Participants 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-min flow rate will be calculated using the conversion of 1.0 g = 1.0 mL. Values should be expressed as mL per minute. Participants should be surveyed regarding whether they would normally chew the submitted gum for at least 20 minutes if unsupervised.
2. **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. A double-blind, crossover design should be used. Two days before the test, the participants should refrain from all oral hygiene procedures to permit biofilm growth for pH determination. Biofilm pH measurements should be made in the morning with participants refraining from all food or drink for at least 6 hours. After the baseline plaque pH has been measured, the participants 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.
3. **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. A one-week washout in between study periods is recommended. 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.

Assessments for efficacy: Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparator. The test chewing gum needs to demonstrate to be at least non-inferior to a standard chewing gum, preferably approved for the Seal for this category. For salivary flow tests, products must show an equivalent or a statistically significant improved performance when compared to the control.

Assessments for safety: Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator.

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. For crossover studies, appropriate statistical models, testing for the effect of period and sequence, should be used.

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