

## Acceptance Program Requirements



# Products for the Cessation of Smoking and Use of Smokeless Tobacco



## 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.

<b>Category:</b>	Products for the Cessation of Smoking and Use of Smokeless Tobacco
<b>Purpose:</b>	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 products which help individuals stop smoking and stop the use of smokeless tobacco can be considered for ADA Acceptance.
<b>Scope:</b>	These requirements apply to gums, lozenges, and patches with active agents intended to help individuals stop smoking and stop the use of smokeless tobacco products.
<b>Notice Regarding Submission of Copyrighted Materials:</b>	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](mailto:adaseal@ada.org).



## 1. SEAL STATEMENT

The following statement applies to smoking cessation products approved under the below-listed criteria:

**FDA-Approved OTC Products Designed for Smoking Cessation:**

“The ADA Council on Scientific Affairs’ Acceptance of (Product Name) is based on its finding that the product can be effective in helping smokers stop smoking, when used as directed. Success is increased when combined with counseling by a dentist or other health care professional.”

**FDA-Approved OTC Products Designed for Smokeless Tobacco Cessation:**

“The ADA Council on Scientific Affairs’ Acceptance of (Product Name) is based on its finding that it can be effective in helping an individual stop using (specify chewing tobacco or snuff), when used as directed. Success is increased when combined with counseling by a dentist or other health care professional.”

Format for product packaging:

- Helps individuals stop using smoking products

## 2. SUBMISSION DIRECTIONS

- Submissions are to be sent in electronic format (email) to [adaseal@ada.org](mailto:adaseal@ada.org). Additional instructions will be provided regarding shipment of necessary samples.
- 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.
- 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.*
- 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.
- Classification of a product under the Acceptance Program is subject to the conditions stated in the Agreement Governing Use of ADA Seal of Acceptance.
- 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 individuals stop using smoking products 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.
  - b) Claims for the product in labeling and in advertising may include that the product help stop smoking or the use of smokeless tobacco, depending on the product involved.
  - c) Claims that the cessation of tobacco use as a result of using the product prevents, reduces, or cures diseases such as periodontitis or oral cancer will not be considered unless adequate clinical studies showing that use of this product does one of these things are submitted.
  - d) Claims that smoking and smokeless tobacco use can exacerbate or lead to disease, such as periodontitis or oral cancer, will be permitted.



- 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. Information submitted shall include assessments of possible systemic and topical toxic effect of the active agent, using appropriate standard toxicological mutagenicity, and if agent proves to be mutagenic, carcinogenicity studies.
- iii. All adverse reactions, systemic or topical, from the clinical studies, as well as their extent and severity, must be reported.

### 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. Product efficacy must be demonstrated by two independent clinical studies of at least 6-month duration.
- iii. Studies should assess the ability of a product with an active agent to help individuals stop smoking or use of smokeless tobacco for a 6-month period following cessation of all tobacco use.
- iv. All published clinical studies assessing the effectiveness of the product must be referenced, including those that do not show an effect. All sponsored clinical studies evaluating the product should be identified at the time of filing.

**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:

- Treating Tobacco Use and Dependence, Clinical Practice Guideline 2008 Update, US DHHS, Public Health Service
- ADA Brand Standards: [https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada\\_seal\\_brand\\_standards\\_nov2024.pdf](https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/research/seal/ada_seal_brand_standards_nov2024.pdf)

## Appendix

### Clinical Protocol Guidelines for Products Used for the Cessation of Smoking and Use of Smokeless Tobacco

The following guidelines are provided for the design and conduct of clinical studies to generate evidence for the evaluation of safety and efficacy of pharmacologic agents used for the cessation of smoking and smokeless tobacco. 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:** Clinical trials should be randomized whenever possible, with participants allocated to treatments through a randomization process. 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. At least one study shall be conducted on a US population. Populations selected for the studies must be representative of individuals for whom the product is intended, that is, individuals who use tobacco cigarettes, chewing tobacco, and snuff. Studies must report all treatment groups, and an attempt should be made to assess the level of compliance of the subjects in the study.

**Number of studies:** At least two studies should be conducted at a different site and including a separate participant pool. Studies are expected to adhere to the CONSORT guideline, and the checklist should be completed and uploaded with the submission. The minimum duration of at least 6-months for clinical studies is necessary to show safety and efficacy of the product.

**Sample size:** A sufficient number of subjects should be enrolled to ensure that appropriate statistical tests can be performed. The protocol should describe how sample size was determined, including all assumptions supporting the calculation and clearly defining the primary and 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.

**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. Each subject will have a complete oral examination to determine eligibility for the study, with both genders and representative age groups included according to intended use. Subjects should not be taking other medications which alter smoking or smokeless tobacco habits. Furthermore, they should not have taken such medications within one month of initiation of the study. Other criteria for inclusion/exclusion of subjects must be provided.

**Test product and comparator:** The test product should be compared with an established, clinically proven positive control. Clear determination is to be made about the goal of the study to show superiority, equivalence or non-inferiority.

**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. Measurements shall include established biochemical markers such as salivary, urinary, serum cotinine levels or expired alveolar carbo monoxide levels. Seven-day point prevalence rates will be taken at least at baseline (prior to the study), immediately following treatment, and at 3- and 6-months following cessation of tobacco use. In addition to the above, self-reported cessation may also be included. Because individuals may substitute other forms of tobacco for the one being evaluated, all tobacco use should be reported. Use of a standardized counseling intervention (across conditions) is acceptable and encouraged. Details of the intervention should be provided (e.g. content overview, number of treatment sessions, timer per session, qualifications of staff delivering counseling, etc.).

**Assessments for efficacy:** Variables assessing efficacy should be clearly described and allow for a comparison between the test product and the comparator. Studies should assess the ability of a product with an active agent to help individuals stop smoking or use of smokeless tobacco for a 6-month period following cessation of all tobacco use. When comparing those who quit all tobacco use in the test and control groups, there should be a statistically significant difference at each post treatment time period in favor of the test group, using a 7-day point prevalence metric. The most likely mechanism(s) of action of the product should be given, with supporting data.

**Assessments for safety:** Variables assessing safety should be clearly described and allow for a comparison between the test product and the comparator. Evidence that the product does not adversely affect oral soft and hard tissues and restorations, should be provided. Subjects should be examined in the course of the studies 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. Information on possible toxic effects and adverse reactions should be included, via standard toxicological profiles. Monitoring for changes in oral microbiota to detect opportunistic or pathogenic organisms should also be performed. It is also recommended that data be provided on the effect of the product, if any, on taste sensation, staining of oral tissue, or other characteristics that may be unique to the active formulation.

**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.

Information to be provided includes expected examiner variance, the targeted alpha and beta values, the estimated drop-out rate, and the targeted treatment differences. Basic documentation should include summary statistics of outcomes and potentially important prognostic variables, by treatment. In multi-center trials, these should be reported separately for each participating center, as well as for all centers combined.

If the trial employs stratified randomization in the design, the analysis should reflect this. The distributions of important prognostic factors should be compared across treatment groups, and statistical adjustment employed where disparities in prognostic variables may have seriously influenced outcome comparisons. In multi-centered trials, the possibility and nature of treatment by center interactions should be examined. Among many possible technical approaches to statistical analysis, analyses of variance or covariance, original categorical analyses and rank analyses are typically considered. Mention of these approaches by no means precludes use of other techniques as appropriate to the study design and variables employed. The Odds Ratio should be calculated and should show a significant difference in abstinence with product use.

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