

## Acceptance Program Requirements



### **Orally-Administered Analgesics for the Temporary Management of Acute Dental Pain**



## 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>	Orally-Administered Analgesics for the Temporary Management of Acute Dental Pain
<b>Purpose:</b>	The Acceptance Program applies to over-the-counter dental products for which safety and usefulness has been established by laboratory, and/or clinical evaluations where appropriate. Accordingly, the purpose of these requirements is to provide a structure upon which orally administered medication used for temporary management of acute dental pain can be considered for ADA Acceptance.
<b>Scope:</b>	These requirements apply to orally administered OTC products used for the temporary management of acute dental pain. Products evaluated using these requirements are thought to manage acute dental pain through analgesic properties. Only products covered under the FDA monograph for acute dental pain are included.
<b>Notice Regarding Submission of Copyrighted Materials:</b>	<p>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 a secure area of the ADA's web site the access to which is restricted to Council members and staff.</p> <p>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 described above and agree to indemnify and hold ADA harmless from any and all claims arising from such publication or distribution.</p> <p>Questions can be directed to <a href="mailto:adaseal@ada.org">adaseal@ada.org</a></p>

## 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 provides is safe and has shown efficacy in helping to temporarily manage acute dental pain, when used as directed.” The ADA recommends patient seek professional help when experiencing dental pain.

Format for product packaging:

- For temporary dental pain reduction

## 2. **SUBMISSION DIRECTIONS**

- A. 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.
- 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.

## 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: for temporary dental pain reduction. 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) All labeling/packaging must be in alignment with over-the-counter (OTC) labeling regulations and the tentative final monograph (TFM) for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products.

## **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. Safety shall also be demonstrated by the absence of irreversible side effects resulting from the use of the product. Documentation of adverse events during all phases of clinical testing are required.
- iii. Only products containing active ingredient(s) included in the FDA tentative final monograph (TFM) for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products will be considered.

## **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, i.e. bioequivalence, PK/PD, etc.
- ii. For substantiation of health-related or medical claims on efficacy, clinical studies will be required. The specific clinical studies needed will depend on the nature of the claim.

- 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:

- ADA Advertising Standards: <https://www.ada.org/publications/advertising-standards>

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