

Acceptance Program Guidelines

Bottled Water with Fluoride

ADA American
Dental
Association®
Council on
Scientific Affairs

2010

Council on Scientific Affairs

Bottled Water with Fluoride

Purpose:

The purpose of these guidelines is to determine the safety and efficacy of bottled water with fluoride being submitted for ADA Acceptance. It is the responsibility of the investigator/manufacturer, hereafter called investigator, to present evidence to show that the product being considered is safe and effective for the delivery of fluoride. Where the term "must or required" appears, it is obligatory to comply with the Guidelines.

Scope:

These guidelines apply to bottled water available to consumers containing from 0.7 to 1.2 ppm fluoride.

I. SUBMISSION DIRECTIONS

1. General Information

- A Submissions should be sent to the Council Office:
Director, Product Evaluations
American Dental Association
Council on Scientific Affairs
211 East Chicago Avenue
Chicago, Illinois 60611-2678
- B Submissions should be sent in triplicate along with 3 market samples of the product from each of 3 separate lots (i.e., packaged as marketed). 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 in 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 valid for five years. The Council upon request will consider renewal of the classification by the manufacturer.
- E Classification of a product under the Acceptance Program is subject to the conditions stated in the contract entitled "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 Email address and Internet address
- F 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).
- G Names and qualifications of scientific personnel responsible for formulation and testing of the product in its manufacturing process.

*4. Summary of Submission

Comprehensive summary of the information submitted on safety and effectiveness of the bottled water with fluoride product.

*5. Product Information

- A Name of product (to be used in listing).
- B Evidence of compliance with all FDA regulations concerning bottled water with fluoride.
- C Claims of efficacy and safety.
 - (i) List of claims of efficacy and safety. All claims of safety and efficacy listed must be documented, including all claims in advertising and promotional materials.
 - (ii) The studies (or parts of studies) that provide documentation for each claim must be identified.
 - (iii) Advertisements must avoid disparagement of other bottled water with fluoride products.
- D Patent title(s) and patent number(s) relating to the product.

E Product composition.

F Instructions including indications and contraindications for use.

G Labeling.

Labeling shall include the fluoride concentration in ppm or mg/L at 22 ± 2 °C. Terms such as "fluoridated", "fluoride added" or "with added fluoride" may be used on the labeling of bottled water containing added fluoride.

Labeling shall also include the following language: Parents and caregivers should consult with their healthcare provider (physician/dentist) to optimize their child's fluoride exposure for good oral health.

H Packaging.

I Promotional materials.

***6. Quality Control Procedures for the Manufacturing and Distribution of the Product**

Describe the quality control procedures applied to the manufacturing of the product. This should include the Quality Control tests used during processing and on the finished product, and assurance that the product meets good manufacturing procedures and that fluoride levels are adjusted between 0.7 and 1.2 ppm depending on the specific geographic area as is done for municipal fluoridated water. (Note: Naturally fluoridated water may even have to be de-fluoridated to meet these criteria.)

***7. Laboratory Evaluation**

Bottled water with fluoride shall be tested for total fluoride concentration and maximum amount of fluoride per container using the procedure outlined in Standard Methods for the Examination of Water and Wastewater (see Reference A) or another validated method of similar sensitivity and accuracy.

8. Comprehensive bibliography

Appropriate references should be included to document statements or comparisons made in the report to the ADA Council on Scientific Affairs.

9. Copies of most significant articles

10. Appendices

Detailed descriptions of test evaluation methods and any other defined areas should be included with any reports submitted to the ADA Council on Scientific Affairs.

III. ACCEPTANCE CRITERIA

Establishment of safety: Evidence shall be provided that the bottled water meets the Bottled Water Code of Practice of the International Bottled Water Association (see Reference B).

Establishment of efficacy: The total fluoride concentration of one bottle of water containing fluoride shall be within the range of 0.7 ppm and 1.2 ppm. The maximum amount of ionic fluoride per liter shall not exceed 1.2 mg at 22 ± 2 °C.

IV. 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 the finding that the product provides an optimum level of fluoride."

V. REFERENCES

- A 4500-F- C. Ion-Selective Electrode Method, Standard Methods for the Examination of Water and Wastewater, 19th Edition, Washington, DC: American Public Health Association, 1995: 4-61
- B International Bottled Water Association, Bottled Water Code of Practice, December, 2009.

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