



Seal of Approval Guidelines

The Approval Program



1. Program Objectives

1.1 To recognise over the counter products with an Oral Health Benefit where products can be established to be safe, efficient and in respect of which advertising claims made by the manufacturer, distributor or applicant can be substantiated and, as an element of that recognition to offer to suppliers a “Seal of Approval” for use in sales promotions directed to the consumer market.

1.2 Through the granting of a “Seal of Approval”, to offer to the general public assurances of safety of consumer products used for oral health benefit and efficacy as to the accuracy of claims made for the product.

1.3 By means of stipulations that are a condition of the granting of the “Seal of Approval”, to ensure that advertising of the recognised products is not misleading.

2. Coverage

The Approval Program shall be limited to over the counter products with an Oral Health Benefit where products can be established to be safe, efficient and in respect of which advertising claims made by the manufacturer, distributor or applicant can be substantiated. Such products marketed to the general public will require certification to comply with International or Australian Standards, or with such other criteria as Federal Council of the Association may determine.

3. Procedure

3.1 Where an International or Australian Standard exists, the product shall be tested for or have evidence of conformity to that Standard as an initial requirement for Approval Program recognition.

3.2 The supplier, having obtained a certificate of compliance under the provisions of paragraph 3.1, shall lodge it with the Federal Secretariat of the Australian Dental Association Inc., together with the following:

- A completed ADA Seal of Approval cover sheet.
- At least four original packages of the material produced for the market.
- A copy of all descriptive and informative material associated with the product, including all promotional material, directions for use, cautions, and the like.
- Evidence of conformity with statutes and regulations of the Commonwealth, States and Territories of Australia that govern the supply to the public of therapeutic or health care products, where applicable to the product submitted.
- Evidence of the safety and efficacy of the product,

including evidence on which the supplier depends to justify claims made for the efficacy of the product (where applicable). Evidence must be of a high quality such as from NATA certified laboratories and appropriately conducted studies. Where such evidence includes scientific papers, copies of the papers shall be supplied. Any documentation not in English shall be accompanied by an English translation.

- An undertaking that all advertising to be used to promote the product shall be in conformity with the Australian Dental Association’s code for advertising of Seal of Approval products, appended to this document, and an undertaking to submit to the Seal of Approval Program, process and the Association’s guidelines.
- An undertaking to immediately advise the Association of any adverse finding relating to the product, or of any evidence whatsoever that may become available to the applicant, relating to the safety or efficacy of the product.
- An undertaking to accept as final the determination of the Association on any application for recognition under the Approval Program.

3.3 An applicant submitting a product for approval shall nominate to the Association a person who is empowered to represent the supply company, group or individual (hereinafter “the supplier”) in all negotiations, and to commit the supplier to undertakings to be given in connection with the approval process, to supply any additional information required by the Association in connection with the approval, and to sign on behalf of the supplier any document, undertaking, agreement or contract in connection with the approval. Four copies, which can be in electronic format, of all applications and supporting data are to be provided to the Association with each application.

4. Use of the Seal

4.1 The Association will award to Approved products a “Seal of Approval” to be available for use in promoting the product to the public. The use of the Seal is governed by the specific guidelines appended to this document.

4.2 It is a condition of the award of the “Seal of Approval” that each and every advertisement in which the Seal is used, or in which reference is made to the Approval Program, shall unless specifically exempted in writing by the Association, include the following words:

“The Australian Dental Association Inc. considers this product to be safe and effective when used for the purpose intended and in accordance with the manufacturer’s instructions”.

5. Fees

5.1 All applications for Approval shall be accompanied by a non-refundable assessment fee. In some instances the panel may seek external advice/assistance to evaluate an application. This will only be conducted with the consent of the applicant and will incur an additional fee.

5.2 An annual licensing fee will be payable.

5.3 An assessment fee will apply to renewals.

6. Renewal

Should the supplier's product have held the Seal for three consecutive years and the Supplier wishes to renew the application of the Seal for the product then the Supplier agrees that the product will be required to undergo a review of the product by the Seal of Approval Panel. Such review will be to ensure that the product remains suitable for retention of the Seal.

7. Withdrawal

The Association may withdraw approval of a product, and the right to use the Seal, where it is established to the Association's satisfaction that there have been breaches of the conditions of approval; or of the Association's advertising code; or where information becomes available that was not available at the time of granting of approval, and it becomes reasonable to assume that the product may not be safe or effective.



Appendix A

Advertising guidelines for the Seal of Approval products

The purpose in allowing the Association's name to be used in commercial advertising is to provide authoritative guidance to the public on matters pertaining to oral health. The Approval Program is designed to provide accurate information on the safety and efficacy of consumer products used for oral health care, and to ensure that:

- All advertising claims made for such products are scientifically accurate and in accord with the entirety of laboratory and clinical test results applicable to the topic.
- Such products are clearly positioned as only one part of any total oral health program.
- The dental profession is not portrayed as promoting or endorsing any specific commercial product, other than the endorsement of safety and efficacy implicit in the approval.

The Association has developed these guidelines for the evaluation of consumer advertising material. However, advertisers will be expected to comply with the spirit of the objectives of the program. The criteria that follow will be used to determine whether any particular advertisement is acceptable to the Association. The Association reserves the right to review and amend the Guidelines according to perceived need.

In the event that a particular advertisement is found unacceptable by the assessing committee, the advertiser has the right of appeal to the Federal Council of the Association whose decision will be final.

1. Clearance Procedures

1.1 All advertising or promotional or packaging materials for Approved Products (those that have acquired the Seal of Approval), that make use of the Seal, must be submitted for review and approved before use.

1.2 Advertising is to be reviewed initially at the storyboard, script or rough copy stage. Advertisers are encouraged to submit rough cuts of video tapes or films to the Association for review. Early review prior to production will help avoid costly changes. Final versions of approved films and video tapes, radio tapes and print-ad layouts must be reviewed before use.

1.3 For its part the Australian Dental Association Inc. undertakes to deal expeditiously with submitted material, and to deal with all applications and related material submitted by an applicant in strict confidence.

2. Validation of Advertising and Promotional Claims

2.1 Claims for Approved Products made in advertising or promotional packaging materials must be accurate in fact and in implication.

2.2 All statements relating to the general subject of oral health must be based on current scientific knowledge.

2.3 In assessing supporting evidence for claims of safety and efficacy the highest level of credibility will be accorded to studies published in reputable scientific journals. Unpublished in-house studies may or may not be accepted, at the Association's discretion.

2.4 At the present level of scientific knowledge no product by itself is capable of eliminating oral diseases. Therefore, advertising for Approved Products should be based on the concept of the product's capacity to contribute to oral health within the context of a total oral health program.

3. Reference to the Profession

Approved Product advertising may not use the word "dentist" or refer to the Australian Dental Association Inc. in such a way as to mislead by implying a relationship with, or endorsement by the Association and its members.

3.1 The Association's name may be used only to vouch for those facts that are directly related to oral health. Any such use must be in good taste and in keeping with professional dignity and in these matters the Association shall be deemed to be the sole arbiter.

3.2 Advertising of Approved Products with products that have not been approved in a single piece of advertising is permissible provided the Seal is clearly associated with the Approved Product only and the advertising copy is approved in advance in accordance with the procedures under this Appendix A.

3.3 The Association's name and/or the Seal and/or the Approval statement may appear in point-of-sale advertising provided the stipulations of 3.1 relating to good taste and dignity are met.

Appendix B

Seal of Approval additional protocols

Mouthwashes

The “Seal of Approval” is to be made available to a limited number of non-prescription mouthwashes with therapeutic effect. Currently, only those mouthwashes claiming effects on supragingival dental plaque and gingivitis will be considered.

This additional protocol is to be read in conjunction with the general protocol, for the “Seal of Approval” above.

In assessing applications for approval under this mouthwash protocol, the Australian Dental Association Inc. will entertain claims based on existing approvals granted by the American Dental Association in accordance with that Association’s corresponding protocol.

Guidelines

Approval of mouthwashes in this category will be based on:

1. Compliance with ISO16408-2004 Dentistry – Oral hygiene products – Oral rinses
2. An assessment of evidence of clinical efficacy and safety in use. This evidence will normally be in the form of reports of independently conducted clinical trials published in reputable and generally-accepted independent, refereed scientific journals.

It will be necessary to demonstrate statistically significant reductions in plaque scores and in gingivitis that can be reliably attributed to the use of the product. Clinical studies shall meet the following requirements:

- Two studies of a minimum of six months duration, conducted by independent investigators.
- The study population shall represent typical product users.
- The product shall be used as in the directions for use and compared with a placebo control, or where applicable, an active control. Crossover or parallel designed studies are acceptable
- Microbiological sampling shall estimate plaque qualitatively to complement indices that measure plaque quantitatively
- Plaque and gingivitis scoring shall be conducted at baseline, 6 months, and at an intermediate period

- The microbiological profile shall demonstrate that pathogenic or opportunistic micro-organisms do not develop over the course of the study
- The toxicological profile shall include carcinogenicity and mutagenicity assays in addition to generally recognized tests for drug safety

Fluoride Containing Toothpastes

The “Seal of Approval” is to be made available to a limited non-prescription fluoride containing toothpastes with therapeutic effect. These additional guidelines primarily relate to the toothpastes’ anti-caries claims. Additional claims for therapeutic effects such as hypersensitivity, gingivitis or calculus reductions will require additional clinical/ laboratory evidence.

This additional protocol is to be read in conjunction with the general protocol, for the “Seal of Approval” above.

In assessing applications for approval under this fluoride containing toothpastes protocol, the Australian Dental Association Inc. will entertain claims based on existing approvals granted by the American Dental Association in accordance with that Association’s corresponding protocol.

Guidelines

1. Approval of fluoride containing toothpastes in this category will be based on:

- i. compliance with ISO 11609 Dentistry -- Toothpastes -- Requirements, test methods and marking, and
- ii. an assessment of evidence of efficacy and safety in use. The level of evidence required is dependent on whether the toothpaste formulation is identical or similar in composition to other ADA accepted products or substantially different.

Similar composition products are required to present the following data compared with a placebo toothpaste (preferred testing methodologies will be supplied on request):

- Total fluoride
- Available fluoride in fresh and aged samples
 - Requirement: 90% of labelled fluoride must be available in fresh and aged samples
 - Aged samples are those at the end of their expiry date. Accelerated ageing is acceptable.
- One minute fluoride release in fresh and aged samples
 - Requirement: 80% of labelled fluoride must be released within one minute of mixing the toothpaste 1:3 with human saliva and/or water.

2. Where there are substantially different toothpaste compositions (e.g., those with a different formulation of fluoride, different abrasives etc.) applicants are required to present the data in item 2.1 and additional clinical evidence showing a significant caries reduction. This evidence will normally be in the form of reports of independently conducted clinical trials published in reputable and generally-accepted independent, refereed scientific journals. Clinical studies shall meet the following requirements:

- Two studies of a minimum of two years duration, conducted by independent investigators (shorter studies utilising more sensitive diagnostic techniques may be considered at the discretion of the panel).
- The study population shall represent typical product users.
- The product shall be used as in the directions for use and compared with an active control (preferably an existing approved toothpaste formulation).
- The toxicological profile shall include carcinogenicity and mutagenicity assays in addition to generally recognized tests for drug safety.

Sugar-Free Chewing Gums

The “Seal of Approval” is to be made available to suitable sugar-free chewing gums. These additional guidelines relate primarily to anti-caries claims for sugar-free chewing gum.

This additional protocol is to be read in conjunction with the general protocol, for the “Seal of Approval” approved by the Federal Council.

In assessing applications for approval under this sugar-free chewing gums protocol, the Australian Dental Association Inc. will entertain claims based on existing approvals granted by the American Dental Association in accordance with that Association’s corresponding protocol.

Guidelines

1. Approval of sugar-free chewing gum in this category will be based on:

- i. An assessment of evidence of efficacy and safety in use. The level of evidence required is dependent on whether the sugar-free chewing gum is identical or similar in composition to other ADA accepted products or substantially different.

ii. Where there are similar composition products, the applicants are required to present the following data compared with a neutral sugar-free chewing gum:

- Quantity and type of acids contained within the gum
- Type of sugar substitutes contained within the gum
- Saliva pH and flow rate following use of the gum at time periods 0-1, 2-4, 6-8 and 10-15 minutes. The recommended method for this analysis has been published by Dawes and Macpherson (Caries Res 1992;26:176-182).

2. Where there are substantially different sugar-free chewing gums (e.g., those with a different formulation of sugar substitutes, acid quantity/type or other therapeutic agents etc.) the applicants are required to present the data in item 1.1 and additional clinical evidence showing prevention of demineralisation or promotion of remineralisation significantly greater than that of a no chewing gum control group. This evidence will normally be in the form of reports of independently conducted clinical trials published in reputable and generally-accepted independent, refereed scientific journals. Clinical studies shall meet the following requirements:

- Two in situ studies of a minimum of ten day duration utilising a crossover design, conducted by independent investigators.
- The study population shall represent typical product users.
- The product shall be used as in the directions for use and compared with a no chewing gum control.
- Products with acidic content or additional therapeutic agents must also be tested against a neutral sugar-free gum formulation (preferably an existing approved sugar-free chewing gum formulation).

APPENDIX C

ADA Seal of Approval Program Schedule of Fees

I. Assessment Charges

Toothpaste, Mouth Rinses

Original submission \$825 incl GST
Supplementary submission* \$275 incl GST
Review-each third year \$580 incl GST

Toothbrushes and dental floss:

Original submission \$385 incl GST
Supplementary submission* \$220 incl GST
Review-each third year \$270 incl GST

Sugar-free chewing gums

Original submission \$825 incl GST
Supplementary / review submission* \$275 incl GST
Review-each third year \$585 incl GST

Food products

Original submission \$825 incl GST
Supplementary / review submission* \$275 incl GST
Review-each third year \$580 incl GST

Water Filters

Original submission \$385 incl GST
Supplementary submission* \$220 incl GST
Review-each third year \$270 incl GST

** A discounted rate will apply where the Panel considers that there are no substantial differences between the product covered by the original submission and a related product with essentially the same formula, configuration or characteristics.*

II. Licensing Charges

Toothpastes, Mouth Rinses \$5,500 incl GST pa
Toothbrushes, Dental Floss \$3,300 incl GST pa
Sugar-free chewing gums \$5,500 incl GST pa
Food Products \$5,500 incl GST pa
Water Filters \$3,300 incl GST pa



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Australian Dental Association

Phone: (02) 9906 4412

Email: fsem@ada.org.au

ada.org.au