

Product Approval Program

Guidelines



NOTE: These guidelines will not constitute approval of the products described in this document. No rights are vested in the applicant pursuant to the lodging of the application form. If the application is approved and the product accepted as part of the Osteopathy Australia Product Approval Program, a written contract will be forwarded to you for execution.

A. OBJECTS

1. The object of the Osteopathy Australia Product Approval Program is to provide authoritative guidance to the public on matters pertaining to the principles and practices of osteopathy. It is the objective of the Osteopathy Australia Product Approval Program to provide information and education directly and indirectly to consumers and suppliers regarding the virtues of the practice of osteopathy and musculoskeletal wellbeing.
2. The Osteopathy Australia Product Approval Program is intended to inspire an interest in and to encourage an awareness of osteopathic practice, it is not the purpose of the Product Program to approve or in any way whatsoever to endorse the commercial benefits of any given product, its designer, manufacturer, supplier or retailer.

B. COVERAGE

3. The Osteopathy Australia Product Approval Program shall be limited to products marketed to the public that are approved by Osteopathy Australia and which comply with any Australian Standard and any other standard or performance specification legislated, prescribed or regulated by State or Federal Government and which otherwise complies with this Program as amended from time to time by the Board of Directors.
4. In no way does the Osteopathy Australia Product Approval Program approve any manufacturer, designer, supplier, retailer or producer. Nor will it approve or endorse the commerciality of any approved products.

C. APPLICATION PROCEDURE

5. An applicant seeking the approval of its product by Osteopathy Australia pursuant to this Program must make a written application complying with each and every requirement of this Product Approval Program as stipulated by the Board of Directors from time to time.
6. The applicant shall apply on the relevant application form and pay the prescribed application fee.
7. The applicant will provide evidence to the satisfaction of Osteopathy Australia that the relevant product complies with any Australian Standard or any other standard or performance specification as is legislated, prescribed or regulated by State or Federal Government and shall undertake to comply with any such standards or performance specifications as they are amended from time to time. It is anticipated that in most circumstances independent tests ought to be carried out on the relevant products and certificate evidence should be included in the application.
8. The applicant shall also provide evidence that component parts of the product comply with all standards and performance specifications as were mentioned in paragraph 7.
9. The applicant shall provide evidence of the safety and osteopathic healthcare qualities of the product, including evidence on which the applicant depends to justify its claims for the product (where applicable). Where such evidence includes scientific papers, copies of the papers shall be supplied (in English).

10. In assessing an application Osteopathy Australia will take into account the quality of the product, its health and safety when used for the intended purpose, the accuracy and adequacy of the instructions and other information provided to users, and the accuracy, factuality and verifiability of the claims made regarding the product.
11. Applications shall provide a comprehensive sales and marketing history and sales forecasts (for the next two years) for each product to be approved by Osteopathy Australia. Osteopathy Australia shall keep that information confidential.
12. An applicant submitting a product for approval shall nominate to Osteopathy Australia a person who is authorised to represent the applicant in all negotiations and to commit the applicant to undertakings to be given in connection with the approval process, to supply any information required by Osteopathy Australia in connection with the approval and to sign on behalf of the applicant any document, undertaking or agreement in connection with the approval.
13. Osteopathy Australia, if satisfied that the product meets all standards and specifications shall evaluate the product to determine that the product has satisfactory qualities of osteopathic healthcare. The applicant will make available one unit of the product to Osteopathy Australia for evaluation.
14. The decision of Osteopathy Australia is final and no reason need be given for rejection of a product. However, Osteopathy Australia may, at its discretion, provide reasons.
15. Each product shall be the subject of a separate application.
16. In addition to the application fee, an evaluation fee may be charged.
17. An applicant having obtained a certificate of approval from Osteopathy Australia will lodge it with Osteopathy Australia together with:
 - (a) A copy of all descriptive and informative material associated with the product, including all promotional material, directions for use, cautions etc.
 - (b) Copies of all evidential material supplied to Osteopathy Australia.
 - (c) Copies of product liability insurance in the joint names of the applicant and Osteopathy Australia to the value of \$10 million or as otherwise determined by the Board of Directors.
 - (d) An undertaking that all advertising to be used to promote the product shall be in conformity with Osteopathy Australia's advertising guidelines and an undertaking to submit to Osteopathy Australia for prior approval advertising copy that includes any reference to the Product Approval Program of Osteopathy Australia.
 - (e) An undertaking to advise Osteopathy Australia of any adverse findings relating to the product, or any evidence that may become available to the applicant relating to the safety or efficiency of the product. Any such matter that is inconsistent with the application which comes to the attention of the applicant will impose an obligation on the applicant to inform Osteopathy Australia and if required by Osteopathy Australia the applicant will take all necessary steps to disassociate Osteopathy Australia from the product. In some circumstances that may require the recall of the product.
 - (f) An undertaking that the applicant shall fully indemnify Osteopathy Australia for any liability debt or obligation including the costs of defending any action incurred by the Association whether jointly or severally with the applicant or otherwise, arising out of any approval or resulting from the manufacture promotion or sale of any approved product.
 - (g) An undertaking that the applicant will at no time without the consent of the approval committee assign lease transfer or otherwise dispose of any rights under the agreement. The approval is not transferable.
18. No product approval shall exclude other applicants of like products from seeking and obtaining approval from Osteopathy Australia.
19. Renewals shall be reviewed by Osteopathy Australia and agreed with the applicant.

20. Osteopathy Australia may withdraw approval of a product, and the right to use the Association name logo or trademark, where it is established to Osteopathy Australia's satisfaction that there have been breaches of the conditions of approval, or of Osteopathy Australia's advertising code and guidelines, or where information becomes available that was not available at the time of granting the approval and it is reasonable to assume the product may not be safe nor meet with the satisfaction of Osteopathy Australia.

D. ADVERTISING GUIDELINES

21. The purpose in allowing Osteopathy Australia's name to be used in commercial advertising is to provide to the public on matters pertaining to osteopathic healthcare.
22. The Osteopathy Australia Product Approval Program is designed to provide accurate information on the safety and advantages of consumer products designed, manufactured, produced or sold consistently with the principles for osteopathic healthcare, and to ensure that:
 - (a) All advertising claims made for such products are clinically accurate and in accord with laboratory and clinical test results applicable to the topic.
 - (b) Such products are clearly positioned as only one part of the total osteopathic health program.
 - (c) The osteopathic profession is not portrayed as promoting or endorsing the commercial benefits of any specific product, other than the approval of the product in so far as the product meets Osteopathy Australia's standards of osteopathic healthcare qualities.
23. Osteopathy Australia has developed these guidelines to evaluate 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 Osteopathy Australia. Osteopathy Australia reserves the right to review and amend the guidelines according to perceived need.
24. In the event that a particular advertisement is found unacceptable by Osteopathy Australia, the advertiser has the right of appeal to the Osteopathy Australia Board of Directors.

E CLEARANCE PROCEDURES

25. All advertising or promotional or packaging materials for Approved Products must be submitted for review and approved before use.
26. 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 Osteopathy Australia for review.
27. Early review prior to production will help to avoid costly changes. Final versions of approved films and video tapes, radio tapes and print advertisement layouts must be reviewed before use.
28. For its part Osteopathy Australia undertakes to deal expeditiously with submitted material, and to deal with all applications and related material by an application in strict confidence.
29. Advertising may not use the word osteopathic or refer to Osteopathy Australia in such a way as to mislead by implying a relationship with, or endorsement by, Osteopathy Australia and its members other than in accordance with this Program.
30. Advertising of approved products with products that have not been approved in a single piece of advertising is permissible provided that Osteopathy Australia's name, logo or trademark is clearly associated with the approved product only and the advertising copy is approved in advance in accordance with the procedures outlined in this document.
31. Osteopathy Australia's name, logo trademark and/or the approval statement may appear in point-of-sale advertising provided all stipulations in those policy are met.
32. Osteopathy Australia will review and respond promptly to advertising clearance requests. Clearance must be in writing and duly signed by an authorised representative of Osteopathy Australia.