

Seal of Acceptance/Approval PROGRAM GUIDELINES

Canadian Podiatric Medical Association 120 Carlton Street, Suite 305 Toronto, ON M5A 4K2

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COMMITTEE

\mathbf{ON}

PODIATRIC MATERIALS AND EQUIPMENT

The Committee on Podiatric Materials and Equipment is charged with the responsibility of reviewing materials and equipment that are used in the practice of podiatric medicine or that influence the foot health of the Canadian public.

The recommendations of this committee are made to the CPMA Board of Directors for final action.

SEAL OF ACCEPTANCE GUIDELINES

I <u>DESCRIPTION OF THE SEAL OF ACCEPTANCE</u>

The Seal of Acceptance (Seal) is granted when evidence of safety and usefulness has been established by appropriately recognized laboratory and/or specifications applicable to equipment and materials under consideration have been met. In addition, the Seal shall only be granted when products allow for normal foot function and quality foot health. Products that are primarily cosmetic shall not be considered acceptable for the Seal.

II PRODUCT CATEGORIES GRANTED SEAL OF ACCEPTANCE

A. Materials

Those materials used in the production of footwear and/or used by the public and/or used by the podiatric physician for the treatment of conditions of the human foot.

B. Equipment

The equipment which is used by the public and/or the podiatric physician for the treatment of conditions of the human foot.

C. Shoes and Hosiery

Those forms of footwear which are used by the public and foot gear used by the podiatric physician.

D. Non-Prescription Therapeutic (Medicinal) Agents

E. Prescription Therapeutic (Medicinal) Agents

III CONDITIONS FOR THE USE OF THE SEAL OF ACCEPTANCE

Companies or individuals whose product(s) have been granted the Seal of Acceptance are expected to support a program of foot health education for the public for the term of approval (three years), and must sign a disclaimer indemnifying the CPMA (see addendum).

IV APPLICATION PROCEDURE FOR THE SEAL OF ACCEPTANCE

A. General Provisions for Acceptance

- 1. All communications with the committee shall be written.
- 2. All communications shall be sent to:
 Seal of Approval Committee
 Canadian Podiatric Medical Association
 120 Carlton Street, Suite 305
 Toronto, ON M5A 4K2
- 3. The identity of members of the committee shall not be disclosed to the applicant.
- 4. Any effort to contact a member of the committee, other than staff of the Chairman, will result in the immediate rejection of the application.
- 5. Any changes in the composition, style, function, name, or intended use of the product(s) shall be immediately communicated to the committee.
- 6. The committee reserves the right to utilize an independent laboratory, institution and/or testing service to confirm any or all claims made by the applicant, the expense of such testing to be borne by the applicant.
- 7. Any adverse effects related to the use of the product(s) reported to the applicant shall be immediately communicated to the committee.
- 8. The committee will not review an application until it is complete.
- 9. Product(s) shall conform to all applicable laws and regulations (Provincial and Federal).
- 10. A \$750 processing fee is required for each submission.

NOTE: All products submitted for consideration will not be returned, unless specified prior to submission.

B. Specific Provisions for Acceptance

1. Materials

- a. name of product(s)
- b. name of manufacturer address telephone number contact person(s)
- c. stated purpose of submission
- d. glossary of terms
- e. intended use(s)
- f. patent(s)
- g. composition, physical and/or chemical properties
- h. research documentation
- i. evidence of safety
- i. evidence of usefulness
- k. evidence of quality control procedures
- 1. names of owners, officers or other individuals authorized to furnish information and represent the manufacturer to the committee
- m. current promotional material(s)
- n. samples of product(s) for evaluation and/or testing
- o. any other material which applicant deems helpful to the committee

2. Equipment

- a. name of product(s)
- b. name of manufacturer address telephone number contact person(s)
- c. stated purpose of submission
- d. glossary of terms
- e. intended use(s)
- f. patent(s)
- g. composition, design research
- h. research documentation
- i. evidence of safety
- i. evidence of usefulness
- k. evidence of quality control procedures
- 1. names of owners, officers or other individuals authorized to furnish information and represent the manufacturer to the committee
- m. names and qualifications of scientific personnel responsible for development and testing of the equipment
- n. current promotional material(s)
- o. samples of product(s) for evaluation and/or testing (in instances when, in the committee's judgment, the equipment is either size or cost prohibitive, this requirement may be modified)
- p. suggested retail price(s)
- q. guarantees or warranties
- r. any other material which applicant deems helpful to the committee

3. Shoes and Hosiery

- a. name of product(s)
- b. name of manufacturer address telephone number contact person(s)
- c. stated purpose of submission
- d. glossary of terms
- e. intended use(s)
- f. patent(s)
- g. composition, (materials and chemicals: i.e., adhesives and/or dyes, and/or fibre analysis when applicable)
- h. research documentation (design, flexibility, sole abrasion, shock absorption, effects of moisture where applicable)
- i. range of available sizes
- j. guarantees or warranties
- k. suggested retail price(s)
- 1. evidence of safety
- m. evidence of usefulness
- n. evidence of quality control procedures
- o. names of owners, officers or other individuals authorized to furnish information and represent the manufacturer to the committee
- p. names and qualifications of scientific personnel responsible for development and testing of the product
- q. current promotional material(s)
- r. samples of modes(s) or style(s) (please contact the committee chairman to determine specific size requirements)
- s. any other material which applicant deems helpful to the committee

V ACTIONS OF APPLICATION

A. ACCEPTABLE

- 1. All information provided has satisfied the conditions for acceptance.
- 2. Seal of Acceptance is granted for 3 years.
- 3. There is an option to renew the Seal of Acceptance when the term expires.

B. UNACCEPTABLE

- 1. Lacks sufficient evidence to be classified as acceptable.
- 2. When evidence is so limited or inconclusive that the product(s) cannot be accurately evaluated.
- 3. When the product(s) is (are) markedly inferior, useless, or potentially harmful to the public.

VI CONDITIONS FOR THE PROMOTION OF THE SEAL OF ACCEPTANCE

- A. Limited to product(s) submitted for evaluation.
- B. Any changes or anticipated changes in the composition, nature, function, name, or use of the product(s) must be reported to the committee immediately.
- C. The manufacturer shall be solely responsible for substantiating all claims of safety and usefulness.
- D. The Seal of Acceptance shall not be used until an appropriate written announcement has been received from the Canadian Podiatric Medical Association.
- E. All advertising or educational material related to the promotion of any product(s) granted the Seal of Acceptance must be submitted to the Committee for approval prior to its use.
- F. The use of the committee's name shall be permitted to inform the profession and/or the public that the product(s) have been found acceptable for their intended purpose.
- G. All advertising materials, devices, labels and other promotional vehicles must be in good taste.
- H. The manufacturer has complied with Section III, "Conditions for the Use of the Seal of Acceptance".

VII CONDITIONS FOR THE TERMINATION OF USE OF THE SEAL OF ACCEPTANCE

- A. An application will/may be considered "withdrawn" if, within six months, conditions of Sections III have not been established.
- B. Failure to comply with all or part of Section VI may result in termination of the Seal of Acceptance.
- C. Any change in the manufacturer of the product(s), may result in termination of the Seal of Acceptance.
- D. Any change(s) in the product(s) or newly discovered evidence which the committee feels is not consistent with its criteria for acceptability may result in termination of the Seal of Acceptance.
- E. If the Seal of Acceptance is terminated, all promotion of the product(s) with reference to the Seal of Acceptance or the Committee must be discontinued within six (6) months.

VIII RENEWAL OF THE SEAL OF ACCEPTANCE

- A. The committee reserves the right to require all, or part of the required information requested in section IV.
- B. A new or continued foot health education program is expected to be presented to the appropriate committee.

IX PUBLIC EDUCATION GRANT SCALE

The fulfillment commitment for a seal holding company usually ranges from \$3,000 to \$6,000 with the determination made by the company in consultation with the CPMA.