1. Objectives of "SDA Seal" program

- 1. To generate and maintain oral health awareness of the public.
- 2. To meet the commercial need of the dental healthcare industry in promoting suitable products to the consumers.
- 3. This program will be offered to the specific products which the companies can give assurance of safety and effectiveness of these products.
- 4. This program will also be offered if the companies can give assurance that advertisements for these products are true and not misleading.
- 5. The SDA Seal is voluntary and while it is a revenue-generating program for SDA, it should not deviate from the objectives as listed above.

2. Requirements for "SDA Seal" applications

The company may appoint one officer to apply on the company's behalf.

The "applicant" in this case will be defined as either the company applying for the SDA Seal or the officer appointed by the said company.

The applicant must:

- 1. Give a written undertaking to aid in generating and enhancing oral health awareness among consumers.
- 2. Submit product specification, ingredient lists and other pertinent information for review and approval.
- 3. Supply objective data from clinical and/or laboratory studies that support the product's safety, effectiveness and promotional claims.
- 4. Provide evidence to assure purity and uniformity of the product, and that the product is manufactured in compliance with recognized international standards or with such other criteria as the Accreditation Committee may determine from time to time
- 5. Submit all advertising, promotional claims and patient education materials for review and approval by the Accreditation Committee and be following the Accreditation Committee's standards for accuracy and truthfulness in advertising.
- 6. Indemnify SDA and its agents from and against all claims, legal proceedings, damages and expenses of any nature which incur in connection with the product(s) bearing the SDA Seal.

3. Guidelines & Procedures for "SDA Seal"

The Guidelines for the "SDA Seal" are provided for a general overview of the program. The Seal may not be used in any way unless it has been officially granted approval by the

Accreditation Committee. Upon termination or expiration of the agreement, regardless of cause, the company is prohibited to use the Seal.

Therapeutic agents, drugs, chemicals, materials, instruments, and equipment that are employed in the diagnosis, treatment or prevention of dental disease may be submitted for evaluation. Conversely, products that do not claim any therapeutic value are not eligible for consideration.

The validity of the Seal is for 3 years and is renewable upon re-application. If there is any change, be it the manufacturer, distributor, percentage or composition of the ingredients of the product, the application for the "SDA Seal" must be resubmitted. Failure to do so will result in the withdrawal automatically.

3.1 Basic requirements for applicants

- 1. Apply in writing, complete with all requirements as stated in the Requirements for the "SDA Seal".
- 2. Provide documentation detailing the company, the nature of business and its directors/shareholders which manufacture/import/distribute the product.
- Furnish evidence or licensing proof from relevant authority that the product is approved to be legally sold in Singapore. Products sold online are prohibited from using the "SDA Seal".
- 4. Assure the Accreditation Committee that the product specification is accurate, and that product packaging and labeling are not misleading.

The Accreditation Committee may also require that additional data be gathered through further testing. The applicant may also be required to furnish other additional information as deemed necessary by the Accreditation Committee.

Once the application is approved, the manufacturer may use the SDA Seal for three years. Renewal of the Seal will be considered by the Council upon request by the manufacturer. An annual licensing fee is payable to SDA for each product application that carries the SDA Seal.

3.2 Submission Procedures

The applicant, having satisfied the Guidelines and Requirements, shall submit the application in writing enclosing the relevant documents to the Accreditation Committee, Singapore Dental Association. Any documentation not in English shall be accompanied by an English translation. All documentation should also be in electronic form, preferably in Microsoft Word or Adobe PDF formats and stored in optical discs.

All applications for the Seal shall be accompanied by a non-refundable administration fee of \$500. An annual licensing fee, depending on the Category, will be payable once the Seal is granted. When a product is granted the SDA Seal, the duration is for 3 years. Renewal of the classification will be considered by the Council upon request by the manufacturer. Renewals of the Seal will be reviewed annually by the Accreditation Committee.

The Accreditation Committee may withdraw approval of a product, and the right to use the Seal, where it is established to the Accreditation Committee's satisfaction that there have been breaches of the conditions of approval: or of the Accreditation Committee's advertising guidelines; 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.

Applicants may submit the documents to:

Singapore Dental Association 320 Serangoon Road #10-13 Centrium Square Singapore 218108

(Attention: Chairperson, Accreditation Committee)

3.3 Confidentiality of Submission Material

All material submitted for Accreditation Committee review is confidential. Any confidential information submitted by a company should be marked as "confidential," "proprietary" or with a similar legend indicating its confidential nature.

If the Accreditation Committee utilizes outside consultants in its review of products, the consultants are required to sign a Confidentiality Agreement or Non-disclosure Agreement. While Accreditation Committee will take all reasonable steps to ensure that such materials are not disclosed or distributed, it will not be liable for any damages resulting from the acts or omissions of the consultants, including but not limited to their failure to abide by the Confidentiality Agreement or Non-Disclosure Agreement.

The applicants are encouraged to engage their own legal counsel to draft their own Confidentiality Agreement or Non-Disclosure Agreement documents at their own expenses.

3

3.4 Additional notes

- 1. The administration fees shall be applicable for a single product including of different sizes/packaging and is not refundable regardless of result of the application.
- 2. Licensing fees shall be on a per annum basis and for a period of 3 years. The renewal fees shall be per annum and for a further period of 3 years. If there are any changes to the composition/ingredient, it shall be treated as a new application.
- Subject to negotiation and SDA's approval, the licensing fees may be packaged as part of advertisement or other fees with the promotion of oral health awareness among consumers as the main theme.
- 4. The product categories are:
 - a. Denture adhesives
 - b. Denture cleaners
 - c. Manual toothbrushes
 - d. Powered toothbrushes
 - e. Mouthwashes & rinses
 - f. Toothpastes
 - g. Floss
 - h. Oral medications, gels & pastes
- SDA reserves the right to amend, delete or reclassify any products categories as it deems fit. SDA will be the final arbiter in the matter relating to classifications of products or type for the purpose of awarding the SDA Seal.

4. Interpretation & Changes to the SDA Seal

Where there is differing interpretation to the guidelines, the applicant should consult the Accreditation Committee for opinions. Should the applicant contest this interpretation, the final arbiter shall be the SDA Council.

The Accreditation Committee reserves the right to make changes to the SDA Seal program at any time at its sole discretion. If the circumstance resulted in termination of the Seal, Accreditation Committee will determine the date by which the license agreement will terminate and will notify affected companies accordingly. All rights of a company to use the SDA Seal will cease upon termination of the license agreement.

The company may appeal to the SDA which shall be the final arbiter in its judgment.

5. Costs, Legal costs & Stamp duty

The applicant shall bear all expenses, legal costs, fees and disbursements (including stamp fees) for the followings:

- 1. In connection with processing an application.
- 2. The preparation and completion of any contracts or agreements for the purpose of awarding the SDA Seal.
- In enforcing any provisions of the SDA Seal Guidelines, Advertising Guidelines and other clauses relating to the SDA Seal program in the event of a breach by the applicant.
- 4. In pursuing legal actions in other matters regarding the SDA Seal program.
- 5. In connection with replying to queries from the public or media, researching or testing products under scrutiny, or defending lawsuit arising from usage of products bearing the Seal.
- 6. For engaging experts, specialists or other professionals in matters arising from Para 5.5.
- 7. For placement of appropriate advertisements as a means of informing the public in matters arising from Para 5.5.

6. Withdrawal of Acceptance & Liability of SDA

The SDA or the Accreditation Committee may on occasion find it necessary to permanently withdraw the SDA Seal from a product or product category. Such decisions may be made at any time at the sole discretion of the SDA or the Accreditation Committee.

Any violation of the Seal Guidelines, Requirements or Agreement is grounds for the withdrawal of the SDA Seal from the Product.

An appeal against the withdrawal should be made in writing to the SDA Council. The SDA Council shall be the final arbiter in such a matter.

The SDA Council, Accreditation Committee, SDA members or agents shall not be held liable for any commercial losses (monetary, goodwill, time and effort, etc) arising from such a withdrawal.