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No. S 95

HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS (ORAL DENTAL GUMS) (AMENDMENT) REGULATIONS 2019

In exercise of the powers conferred by sections 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Oral Dental Gums) (Amendment) Regulations 2019 and come into operation on 2 April 2019.

Amendment of regulation 10

2. Regulation 10(2) of the Health Products (Oral Dental Gums) Regulations 2016 (G.N. No. S 539/2016) (called in these Regulations the principal Regulations) is amended by deleting the words "application and approval fees" in sub-paragraph (c) and substituting the words "application fee".

New regulation 10A

3. The principal Regulations are amended by inserting, immediately after regulation 10, the following regulation:

"Application for transfer of approval of an advertisement

10A.—(1) For the purposes of section 21(1) of the Act, a person must not transfer an approval of an advertisement granted under regulation 9 (called in this regulation an advertisement approval) to another person, unless the transfer of the advertisement approval is approved by the Authority (called in this regulation a transfer approval).

- (2) An application for a transfer approval must
 - (a) be made in the form and manner specified on the Authority's website;
 - (b) be accompanied by such particulars, information or material as the Authority may require; and
 - (c) be accompanied by the relevant application fee specified in the Schedule.
- (3) Any transfer approval granted by the Authority under this regulation
 - (a) may be subject to such conditions as the Authority may impose; and
 - (b) takes effect from such date as the Authority may specify in its transfer approval.
- (4) To avoid doubt, a transfer approval granted by the Authority under this regulation in respect of an advertisement does not extend the period of the advertisement approval granted for that advertisement under regulation 9.".

Amendment of regulation 11

4. Regulation 11 of the principal Regulations is amended by deleting the words "9 and 10" and substituting the words "9, 10 and 10A".

Amendment of regulation 12

5. Regulation 12 of the principal Regulations is amended by deleting the words "9 and 10" and substituting the words "9, 10 and 10A".

Amendment of regulation 28

6. Regulation 28(2) of the principal Regulations is amended by inserting, immediately after the words "variation of an approved advertisement" in sub-paragraph (b), the words "or transfer of approval of an advertisement".

Deletion and substitution of Schedule

7. The Schedule to the principal Regulations is deleted and the following Schedule substituted therefor:

"THE SCHEDULE

Regulations 9(2)(c), 10(2)(c), 10A(2)(c), 24(3)(d), 25(2)(d) and 28

FEES

1.	Application fee for, or to renew, a manufacturer's licence	\$820
2.	Application fee for, or to renew, an importer's licence	\$820
3.	Application fee for, or to renew, a wholesaler's licence	\$820
4.	Application fee for, or to renew, an importer's licence and a wholesaler's licence	\$1,030
5.	Application fee for registration of an oral dental gum	\$16
6.	Registration fee for an oral dental gum	Nil
7.	Annual retention fee for registration of an oral dental gum	\$11
8.	Application fee for the Authority's approval of any change affecting a licence mentioned in regulation 24(1) or (2)	\$16
9.	Application fee for the Authority's approval of any change concerning a registered oral dental gum mentioned in regulation 25(1)	\$16
10.	Application fee for the Authority's approval of —	
	(a) an advertisement using light and sound projection	\$206
	(b) any other advertisement that is not a sales promotion	\$103
11.	Application fee for the Authority's approval of a sales promotion, in addition to the fee in item 10, if any	\$103

12.	Fee for the Authority's approval, for the first year, of —	
	(a) an advertisement using light and sound projection	\$103
	(b) any other advertisement that is not a sales promotion	\$103
13.	Fee for the Authority's approval, for the first year, of a sales promotion, in addition to the fee in item 12, if any	\$103
14.	Fee for renewal of the Authority's approval, for each subsequent year, of —	
	(a) an advertisement using light and sound projection	\$309
	(b) any other advertisement that is not a sales promotion	\$206
15.	Fee for renewal of the Authority's approval, for each subsequent year, of a sales promotion, in addition to the fee in item 14, if any	\$206
16.	Application fee for variation of an approved advertisement or approved sales promotion	\$52
17.	Application fee for the transfer of approval from one person to another of one or more advertisements or sales promotions	\$16

Made on 13 February 2019.

KANDIAH SATKUNANANTHAM

Chairman, Health Sciences Authority, Singapore.

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(To be presented to Parliament under section 72(5) of the Health Products Act).