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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (ORAL DENTAL GUMS) REGULATIONS 2016

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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:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Health Products (Oral Dental Gums) Regulations 2016 and come into operation on 1 November 2016.

Definitions

2. In these Regulations, unless the context otherwise requires —

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"container", in relation to any oral dental gum, means an article or packaging immediately covering the oral dental gum, including any bottle, bubble pack, blister pack, strip pack, wrapper or other similar article, but does not include —

(*a*) an article for ingestion; or

(*b*) an outer package or other packaging in which the container is further enclosed;

"expiry date", for any oral dental gum, means the date after which, or the month and year after the end of which, the oral dental gum should not be used;

"licensed healthcare institution" means a medical clinic or private hospital that is licensed under the Private Hospitals and Medical Clinics Act (Cap. 248);

"licensed retail pharmacy" means premises specified in a pharmacy licence issued under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"licensee", in relation to any oral dental gum, means the holder of a manufacturer's licence, an importer's licence or a wholesaler's licence for the oral dental gum;

"oral dental gum" means a health product categorised as an oral dental gum in the First Schedule to the Act;

"prescription-only oral dental gum" means an oral dental gum that is registered under the classification of "prescription-only oral dental gum" in the Register of Health Products;

"qualified pharmacist" means a person who —

(*a*) is registered as a pharmacist under the Pharmacists Registration Act (Cap. 230);

(*b*) holds a valid practising certificate granted under section 23 of that Act; and

(*c*) is in active practice as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008);

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

"sales promotion" means any advertisement of an oral dental gum in the form of —

(*a*) a sales campaign (including door-to-door sales and price discounts);

(*b*) an exhibition;

(*c*) a competition; or

(*d*) any other activity meant to introduce, publicise or raise the profile, public awareness or visibility of, the oral dental gum,

for the purpose of promoting the sale or use of the oral dental gum;

"supply by retail sale" means sale by retail and includes exposure or display as an invitation to treat.

PART 2

SUPPLY OF ORAL DENTAL GUMS

Supply by retail sale of oral dental gums

3.—(1) For the purposes of section 17(1) of the Act, a person must not supply by retail sale an oral dental gum unless —

(*a*) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

(*b*) the supply is made at or from a licensed healthcare institution supplying the oral dental gum to a patient of that healthcare institution, and in accordance with the written instructions of a qualified practitioner practising in that healthcare institution; or

(*c*) the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner.

(2) In addition to the requirements in paragraph (1)(*a*), a person who supplies by retail sale a prescription-only oral dental gum under that paragraph must do so in accordance with a valid prescription given by a qualified practitioner.

(3) For the purposes of paragraph (2), a prescription is valid only if the prescription —

(*a*) is written and signed by a qualified practitioner; and

(*b*) contains all of the following particulars:

(i) the date of the prescription;

(ii) the name and address of the qualified practitioner giving the prescription;

(iii) the name, identity card or other identification document number, and contact details, of the individual to whom the prescription relates;

(iv) the name and total amount of the prescribed oral dental gum to be supplied to the individual.

(4) If the person who supplies by retail sale a prescription-only oral dental gum in paragraph (2) is a qualified pharmacist or a person acting under the supervision of a qualified pharmacist, that person must —

(*a*) label every container, or every outer package enclosing a container, of the prescription-only oral dental gum with all of the following information in English:

(i) the name of the individual to whom the oral dental gum is to be supplied;

(ii) the name, address and any identification number or logo of the licensed retail pharmacy where the oral dental gum is supplied;

(iii) the date that the oral dental gum is supplied;

(iv) the directions for use of the oral dental gum;

(v) the name of the oral dental gum;

(*b*) mark the prescription in a manner so as to permanently attach to the prescription that person's name, the address of the licensed retail pharmacy and the date of the supply; and

(*c*) retain the prescription for a period of at least 2 years after the date of the supply.

Records of supply by retail sale of oral dental gums

4.—(1) For the purposes of section 17(2)(*f*) of the Act, a person who supplies by retail sale an oral dental gum must keep at the

premises where or from which the oral dental gum is supplied a record, complying with paragraphs (2) and (3), of every such supply.

(2) The record in paragraph (1) must contain all of the following particulars:

(*a*) the date of supply;

(*b*) the name, identity card or other identification document number, and contact details, of the individual to whom the oral dental gum is supplied;

(*c*) the name and the total amount of the oral dental gum supplied;

(*d*) if the oral dental gum is a prescription-only oral dental gum, the name and address of the qualified practitioner who signed the prescription.

(3) The record in paragraph (1) must be made on the day on which the oral dental gum is supplied and must be kept for a period of at least 2 years after the date of the supply.

(4) A supplier must make available for inspection by the Authority at all reasonable times any record made under paragraph (1).

PART 3

PRESENTATION OF ORAL DENTAL GUMS

Display of information on oral dental gums

5. For the purposes of section 18(1) of the Act, every container of an oral dental gum, or every outer package enclosing a container of an oral dental gum, must be labelled with all of the following information:

(*a*) the name of the oral dental gum or an appropriate description of the oral dental gum;

(*b*) the list of ingredients in accordance with regulation 6;

(*c*) if the oral dental gum is manufactured in Singapore, the name and address of the manufacturer of the oral dental gum;

(*d*) if the oral dental gum is imported, the name and address of the importer;

(*e*) the batch reference given by the manufacturer of the oral dental gum to the batch of which the oral dental gum forms a part;

(*f*) the expiry date of the oral dental gum;

(*g*) all precautions to be observed in the use of the oral dental gum.

List of ingredients

6.—(1) For the purposes of regulation 5(*b*), every ingredient of an oral dental gum must, subject to paragraphs (2) to (5), be listed by volume or by mass in descending order using nomenclature from the latest edition of any of the following publications:

(*a*) the British Pharmacopoeia;

(*b*) the Chemical Abstracts Service;

(*c*) the Codex Alimentarius;

(*d*) the Food Chemicals Codex;

(*e*) the United States Pharmacopoeia.

(2) Where an oral dental gum contains tartrazine, it must be specified in the list of ingredients as —

(*a*) tartrazine;

(*b*) colour (102); or

(*c*) colour (FD and C Yellow No. 5).

(3) Any flavour used as an ingredient of an oral dental gum must be specified in the list of ingredients by the word "flavour" or the ingredients of the flavour.

(4) A substance need not be specified in the list of ingredients if it is only present as a trace which could not reasonably have been removed during or after the manufacture of the oral dental gum.

(5) The Authority may, on the application of a person who intends to supply an oral dental gum, allow any ingredient of the oral dental

gum to be specified as "other ingredient" in the list of ingredients if the Authority is satisfied that —

(*a*) revealing the ingredient in the list of ingredients would prejudice a trade secret; and

(*b*) including the ingredient in the oral dental gum is unlikely to be harmful to any consumer.

(6) In this regulation, "flavour" means a substance used as an ingredient of any oral dental gum solely to impart a taste to the oral dental gum.

Manner in which particulars are to be stated

7.—(1) For the purposes of section 18(1) of the Act, all of the information required by this Part to be labelled on every container of an oral dental gum or every outer package enclosing a container of an oral dental gum must —

(*a*) be provided in English;

(*b*) be legible and indelible; and

(*c*) appear conspicuously in a prominent position on such container or package so as to be clearly visible to a person who intends to purchase or use the oral dental gum.

(2) Where the container for the oral dental gum is in the form of a bubble pack, blister pack or other sealed unit and is part of a continuous series comprising a sheet or strip of like containers, regulation 5 is taken to have been complied with if the information required to be stated is printed, displayed or otherwise marked at prominent positions at frequent intervals on the sheet or strip of such containers.

PART 4

ADVERTISEMENT OF ORAL DENTAL GUMS

Prohibition against advertisement of prescription-only oral dental gum

8.—(1) For the purposes of section 21(1) of the Act, no advertisement of an oral dental gum by a non-public sector person may relate to a prescription-only oral dental gum.

(2) In this regulation, "non-public sector person" means a person other than —

(*a*) a public authority established by a public Act for a public purpose; or

(*b*) a person authorised by the Minister.

No advertisement of oral dental gums except with prior approval of Authority

9.—(1) Subject to the prohibition in regulation 8, for the purposes of section 21(1) of the Act, a person must not advertise or cause to be advertised any oral dental gum in an advertisement, unless the advertisement is approved by the Authority.

(2) An application for, or to renew, the Authority's approval of any advertisement 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 and approval fees specified in the Schedule.

(3) Any approval by the Authority under this regulation —

(*a*) may be subject to such conditions as the Authority may impose; and

(*b*) is valid for a period of one year after the date on which the approval is granted or renewed, unless the approval is cancelled earlier under section 27 of the Act.

Application for variation of approved advertisement

10.—(1) For the purposes of section 21(1) of the Act, a person must not make any variation to the contents of an advertisement approved by the Authority under regulation 9, unless the variation is approved by the Authority.

(2) An application for variation of an approved advertisement 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.

[S 95/2019 wef 02/04/2019]

(3) If the Authority approves any variation of an approved advertisement, the variation —

(*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 approval of the variation.

(4) To avoid doubt, the variation under paragraph (3) does not extend the period of approval of an advertisement under regulation 9.

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.

[S 95/2019 wef 02/04/2019]

Exception for trade, business or profession

11. Regulations 8, 9, 10 and 10A do not apply to an advertisement of an oral dental gum if the advertisement —

(*a*) is directed exclusively at a person who may lawfully supply any oral dental gum in the course of the person's trade, business or profession; and

(*b*) is not accessible to the general public.

[S 95/2019 wef 02/04/2019]

Exception for trade advertisement

12. Regulations 8, 9, 10 and 10A do not apply to an advertisement of an oral dental gum if the advertisement —

(*a*) is in a catalogue, price list or other document for the purpose of supplying the oral dental gum by wholesale; and

(*b*) does not contain any recommendation relating to the use of the oral dental gum other than as part of the name of the oral dental gum.

[S 95/2019 wef 02/04/2019]

Sales promotions

13. To avoid doubt, a sales promotion is an advertisement to which this Part applies.

PART 5

MATTERS RELATING TO LICENCES AND REGISTRATION

Requirements for issue of importer's licence

14. For the purposes of section 24(2)(*a*)(i) of the Act, the requirements that must be satisfied for the issue, to an applicant, of an importer's licence for an oral dental gum are —

(*a*) that the applicant is a fit and proper person to be issued with the licence; and

(*b*) that the applicant is —

(i) a registrant of the oral dental gum to be imported; or

(ii) otherwise authorised by the registrant of the oral dental gum to import that oral dental gum.

Requirement for registration of oral dental gums

15. For the purposes of section 30(2)(*a*)(iii) of the Act, the Authority may register any oral dental gum if the Authority is satisfied, based on the formulation and specifications of the oral dental gum, that the oral dental gum is safe for its intended use.

PART 6

DUTIES OF MANUFACTURERS, IMPORTERS, ETC., OF ORAL DENTAL GUMS

Division 1 — General duties

Duty to comply with enforcement requirements

16.—(1) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are used for the manufacture, supply or storage of oral dental gums; and

(*b*) any conveyance that is being used for the transport of oral dental gums.

(2) An enforcement officer conducting a routine inspection under paragraph (1) may —

(*a*) require any person having possession or control of any oral dental gum that is found during the inspection to furnish, without charge, a sample of such oral dental gum for the Authority's examination; and

(*b*) take or cause to be taken any photograph of —

(i) the premises or conveyance mentioned in paragraph (1); or

(ii) any property or material found on the premises or in the conveyance.

Duty to maintain records of defects and adverse effects

17.—(1) Every licensee or registrant of an oral dental gum must —

(*a*) maintain a record of every event or other occurrence that reveals any defect in the oral dental gum or that concerns any adverse effect arising from the use of the oral dental gum; and

(*b*) produce such record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person mentioned in paragraph (1) must ensure that every record mentioned in that paragraph —

(*a*) contains all of the following information:

(i) the name or description of the oral dental gum which is defective or of which an adverse effect has arisen from its use;

(ii) the date on which the person first became aware of the event or occurrence;

(iii) the identification number or mark (including the control number, lot number, batch number or serial number) of the oral dental gum;

(iv) the nature of the defect or adverse effect;

(v) any other information that the Authority may specify in writing; and

(*b*) is retained for at least 2 years after the expiry date of the oral dental gum.

(3) A person who fails to comply with paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A person who, in compliance or purported compliance with paragraph (1) or (2), furnishes the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to report defects and adverse effects

18. For the purposes of section 42(1) of the Act, every manufacturer, importer, supplier or registrant of an oral dental gum must, within 7 days after becoming aware of —

(*a*) any defect in the oral dental gum; or

(*b*) any adverse effect that has arisen or can arise from the use of the oral dental gum,

report the defect or adverse effect (as the case may be) to the Authority.

Duty to notify Authority concerning recall

19.—(1) For the purposes of section 44(1) of the Act, every manufacturer, importer, supplier or registrant of an oral dental gum who intends to recall the oral dental gum must immediately, but in any case no later than 24 hours before the start of the intended recall, notify the Authority of the intended recall, and the reasons for the intended recall.

(2) The notice in paragraph (1) must be made in the form and manner specified on the Authority's website.

(3) Where the Authority has been notified of the intended recall of an oral dental gum under paragraph (1), the Authority may by written notice require the manufacturer, importer, supplier or registrant of the oral dental gum to do either or both of the following:

(*a*) investigate the matter occasioning the recall of the oral dental gum and provide a report of the findings of the investigation;

(*b*) take such other measures as the Authority thinks necessary.

(4) A person to whom a notice in paragraph (3) is given must comply with the notice at the person's own cost and within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice.

(5) A person who fails to comply with paragraph (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Division 2 — Duties specific to licensees

Duty of holder of manufacturer's licence

20. Without prejudice to any other provision in this Part, a holder of a manufacturer's licence for an oral dental gum —

(*a*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities as are necessary for carrying out, in accordance with the holder's licence, such stages of the manufacture of the oral dental gum as are undertaken by the holder;

(*b*) must not carry out any stages of manufacture of the oral dental gum in any premises not specified in the holder's licence;

(*c*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the oral dental gum as are necessary to prevent the deterioration of the oral dental gum while it is in the holder's ownership, possession or control;

(*d*) must only use the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority, for handling or storing the oral dental gum;

(*e*) must carry out, or arrange for a testing laboratory as specified in the holder's licence to carry out, tests on the oral dental gum to ensure that the oral dental gum complies with the specifications for that oral dental gum as registered under the Act;

(*f*) must conduct all manufacturing operations in such a way as to ensure that the oral dental gum is of the correct identity and complies with the specifications for that oral dental gum as registered under the Act;

(*g*) must ensure that any test for determining compliance with the specifications for the oral dental gum as registered under the Act is, unless otherwise provided in the holder's

licence, applied to samples taken after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the Authority; and

(*h*) must maintain records of the following information for at least one year after the expiry date of the oral dental gum, or 5 years after the date of manufacture of the oral dental gum, whichever is the longer:

(i) such information relating to the oral dental gum and its manufacture as the Authority may specify in the holder's licence;

(ii) the manufacture of each batch of the oral dental gum and of the tests carried out on every such batch, in the manner specified in the holder's licence.

Duty of holder of importer's licence

21. Without prejudice to any other provision in this Part, a holder of an importer's licence for an oral dental gum —

(*a*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling and storage of the oral dental gum as are necessary to prevent the deterioration of the oral dental gum while it is in the holder's ownership, possession or control; and

(*b*) must not use, for any purpose mentioned in paragraph (*a*), any premises other than the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority.

Duty of holder of wholesaler's licence

22. Without prejudice to any other provision in this Part, a holder of a wholesaler's licence for an oral dental gum —

(*a*) may only supply the oral dental gum by wholesale to a person who may lawfully supply the oral dental gum in accordance with the Act;

(*b*) must provide such information as required by the Authority concerning the type of oral dental gum that the holder handles, stores or distributes;

(*c*) must provide and maintain, or ensure the provision and maintenance of, such staff, premises, equipment and facilities for the handling, storage and distribution of the oral dental gum as are necessary to prevent the deterioration of the oral dental gum while it is in the holder's ownership, possession or control; and

(*d*) must not use, for any purpose mentioned in paragraph (*c*), any premises other than the premises specified in the holder's licence, or such other premises as may be approved from time to time by the Authority.

Offence for contravention of duties

23. A licensee who fails to comply with regulation 20, 21 or 22 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes affecting licence

24.—(1) Subject to paragraph (2), a licensee must obtain the approval of the Authority for any change or proposed change to any particulars furnished by the licensee to the Authority in relation to the application for the licensee's licence.

(2) A licensee must obtain the prior approval of the Authority before making any change that significantly affects the activities of the licensee that are authorised by that licence.

(3) An application for the Authority's approval under paragraph (1) or (2) must —

(*a*) be made in the form and manner specified on the Authority's website;

(*b*) be submitted within such time as the Authority may specify in the conditions of the licence;

(*c*) be accompanied by such particulars, information, documents or samples as the Authority may require;

(*d*) be accompanied by the relevant fee specified in the Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the licensee verifying any information contained in or relating to the application.

(4) For the purposes of paragraph (2), a change that significantly affects the activities of a licensee that are authorised by the licensee's licence includes (but is not limited to) a change of one or more of the following:

(*a*) the premises where the licensee operates;

(*b*) the facilities and equipment used by the licensee;

(*c*) the operations and processes carried out by the licensee.

(5) A licensee who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(6) A licensee who —

(*a*) fails to comply with paragraph (2); or

(*b*) in compliance or purported compliance with paragraph (3), furnishes the Authority with any information which the licensee knows is false or misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Division 3 — Duties specific to registrants

Changes concerning registered oral dental gum

25.—(1) A registrant of an oral dental gum must obtain the prior approval of the Authority before effecting —

(*a*) any change to any particulars provided in relation to the registration of the oral dental gum, including but not limited to the specifications, ingredients, formulation, composition or presentation of the oral dental gum; or

(*b*) any change that may affect the safety of the oral dental gum.

(2) An application for the Authority's approval under paragraph (1) must —

(*a*) be made in the form and manner specified on the Authority's website;

(*b*) be submitted within such time as the Authority may specify in the conditions of the registration of the oral dental gum;

(*c*) be accompanied by such particulars, information, documents or samples as the Authority may require;

(*d*) be accompanied by the relevant fee specified in the Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the registrant verifying any information contained in or relating to the application.

(3) A registrant who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A registrant who —

(*a*) in compliance or purported compliance with paragraph (2), furnishes the Authority with any information under that paragraph which the registrant knows is false or misleading; or

(*b*) supplies or causes to be supplied any oral dental gum that is subject to the proposed change before the Authority has given its approval for the change,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Submission of samples for testing

26.—(1) If required by the Authority, a registrant of an oral dental gum must, at the registrant's expense and in accordance with the Authority's written notice in paragraph (2), submit samples of the oral dental gum, to which the registrant's registration relates, to a testing laboratory for testing.

(2) The Authority's written notice may specify —

(*a*) the particulars or description of the samples of the oral dental gum which a registrant must submit for testing;

(*b*) the testing laboratory to which a registrant must submit the samples for testing; and

(*c*) the time by which a registrant must submit the samples to the testing laboratory for testing.

(3) A registrant who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A registrant who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any information which the registrant knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Information on validity of data submitted to or considered by Authority

27.—(1) A registrant of an oral dental gum must, within 15 days after receiving any information that adversely affects the validity of any data relating to the safety of the oral dental gum furnished by the registrant to the Authority at the time of the application to register the oral dental gum, inform the Authority of such information.

(2) A registrant who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) A registrant who, in compliance or purported compliance with paragraph (1), furnishes the Authority with any information which the registrant knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

PART 7

MISCELLANEOUS

Fees

28.—(1) The fees specified in the Schedule are payable in respect of the matters set out in that Schedule.

(2) The times at which the fees specified in the Schedule are to be paid to the Authority, other than the fees mentioned in paragraphs (3) and (4), are as follows:

(*a*) for an application fee in respect of any licence for, registration of, or change concerning an oral dental gum mentioned in regulation 24(1) or (2) or 25(1), when the application for the licence, registration or change (as the case may be) is submitted to the Authority;

(*b*) for an application fee and an approval fee in respect of any advertisement, including any variation of an approved advertisement or transfer of approval of an advertisement, when the application for the advertisement is submitted to the Authority.

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(3) For the purposes of section 31(*a*) of the Act, the prescribed retention fee is set out in the Schedule and is payable on or before each anniversary of the date of the registration of the oral dental gum.

(4) For the purposes of section 37(2) of the Act, the Authority may cancel the registration of any oral dental gum if the prescribed retention fee is not paid within 60 days after the anniversary of the date of the registration of the oral dental gum.

(5) The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee payable or paid under these Regulations.

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

THE SCHEDULE — *continued*

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

[S 95/2019 wef 02/04/2019]

Made on 27 October 2016.

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).