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FOOD AND DRUGS ACT

Whereas, pursuant to section 30.62 of the *Food and Drugs Act*, the Minister of Health has consulted with any persons that the Minister considers to be interested in the matter;

Therefore, the Minister of Health, pursuant to subsections 30.61(1)[footnote a] and 30.63(1)[footnote a] of the *Food and Drugs Act* [footnote b], makes the annexed *Fees in Respect of Drugs and Medical Devices Order*.

Ottawa, May 3, 2019

Ginette C. Petitpas Taylor
Minister of Health

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PART 1

General

Interpretation

Definitions

1 (1) The following definitions apply in this Order.

entity has the meaning assigned by the definition *organization* in section 2 of the *Criminal Code*. (*entité*)

fiscal year means

- **(a)** for the purposes of sections 16, 17, 25, 26, 49, 53, 57, 66, 67, 74 and 79, the fiscal year of a person that provides information under that section or of a person with which the person is affiliated; and
- **(b)** for the purposes of any other section, the period beginning on April 1 in one year and ending on March 31 in the next year. (*exercice*)

performance standard means the document entitled *Performance Standards for the Fees in Respect of Drugs and Medical Devices Order*, published by the Government of Canada, dated November 22, 2018. (*norme de rendement*)

small business means a person in respect of which either of the following criteria applies:

- **(a)** the total of the number of employees of the person and of the persons with which the person is affiliated is fewer than 100; or
- **(b)** the total of the gross revenue of the person and of the persons with which the person is affiliated is $30,000 or more but less than $5 million. (*petite entreprise*)

Other words and expressions

(2) Unless the context otherwise requires, other words and expressions used in this Order have the meanings assigned to them by the *Food and Drug Regulations* or the *Medical Devices Regulations*, as the case may be.

Affiliation

(3) For the purposes of this Order,

- **(a)** one entity is affiliated with another entity if one of them is the subsidiary of the other or both are subsidiaries of the same entity or each of them is controlled by the same entity or individual;
- **(b)** if two entities are affiliated with the same entity at the same time, they are deemed to be affiliated with each other; and
- **(c)** an individual is affiliated with an entity if the individual controls the entity.

Subsidiary entity

(4) For the purposes of this Order, an entity is a subsidiary of another entity if it is controlled by that other entity.

Control

(5) For the purposes of this Order,

- **(a)** a corporation is controlled by an entity or an individual if
  - **(i)** securities of the corporation to which are attached more than 50% of the votes that may be cast to elect directors of the corporation are held, directly or indirectly, whether through one or more subsidiaries or otherwise, other than by way of security only, by or for the benefit of that entity or individual, and
  - **(ii)** the votes attached to those securities are sufficient, if exercised, to elect a majority of the directors of the corporation; and
- **(b)** an entity other than a corporation is controlled by an entity or individual if the entity or individual, directly or indirectly, whether through one or more subsidiaries or otherwise, holds an interest in the entity that is not a corporation that entitles them to receive more than 50% of the profits of that entity or more than 50% of its assets on dissolution.

Deemed affiliation

(6) For the purposes of this Order, if it may reasonably be considered that one of the main reasons for the separate existence of two or more corporations is so that one of them meets the applicable conditions for a remission of a fee fixed under this Order for which only small businesses are eligible, the two or more corporations are deemed to be affiliated with each other.

Purpose

Purpose — fees

2 (1) The purpose of this Order is to fix the fees for the following:

- **(a)** in respect of drugs for human use and drugs for veterinary use only, the examination of a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission referred to in section C.08.002, C.08.002.1 or C.08.003 of the *Food and Drug Regulations*, as the case may be, an application in respect of an establishment licence filed under those Regulations or an application for a drug identification number filed under section C.01.014.1 of those Regulations;
- **(b)** in respect of drugs for veterinary use only, the examination of a notification for a veterinary health product filed under subsection C.01.615(1) of the *Food and Drug Regulations*, a preclinical submission filed under subsection C.08.005(1) of those Regulations, information filed under section C.08.010 of those Regulations for the purpose of obtaining a letter of authorization, information and material filed under section C.08.014 of those Regulations for the purpose of obtaining an experimental studies certificate, information and material filed with the Minister in respect of a notifiable change or a protocol filed with the Minister;
- **(c)** the right to sell a drug under the *Food and Drug Regulations*; and
- **(d)** the examination of an application in respect of a medical device licence, the right to sell a medical device or the examination of an application in respect of an establishment licence under the *Medical Devices Regulations*.

Purpose — remission

(2) The purpose of this Order is also to remit, in whole or in part, certain of those fees.

Non-application

Non-application

3 (1) This Order does not apply in respect of

- **(a)** publicly funded health care institutions;
- **(b)** branches or agencies of the Government of Canada or of the government of a province; or
- **(c)** drugs that are the subject of an extraordinary use new drug submission filed under section C.08.002.01 of the *Food and Drug Regulations* or of an abbreviated extraordinary use new drug submission filed under section C.08.002.1 of those Regulations.

Definition of *publicly funded health care institution*

(2) For the purposes of subsection (1), ***publicly funded health care institution*** means an institution that is funded by the Government of Canada or the government of a province and that is

- **(a)** licensed, approved or designated by a province in accordance with the laws of the province to provide care or treatment to persons or animals suffering from any form of disease or illness; or
- **(b)** owned or operated by the Government of Canada or the government of a province and that provides health services.

Annual Adjustment of Fees

Adjustment of fees

4 (1) Beginning on April 1, 2021, every fee set out in this Order is to be adjusted in each fiscal year on April 1 by the percentage change over 12 months in the April All-items Consumer Price Index for Canada, as published by Statistics Canada under the *Statistics Act*, for the previous fiscal year and rounded up to the nearest dollar.

Formula

(2) In the case of a fee that is payable under any of Divisions 1 to 5 of Part 2 or Division 1 of Part 3 in a fiscal year that is not set out in the applicable schedule, the amount of the fee is to be calculated, on April 1 of the fiscal year, in accordance with the following formula and rounded up to the nearest dollar:

Fee = A + (A × B)

where

- **A** is the amount of the fee that was payable in the previous fiscal year; and
- **B** is the percentage change over 12 months in the April All-items Consumer Price Index for Canada, as published by Statistics Canada under the *Statistics Act*, for the previous fiscal year.

Requests for Information — Remissions for Small Businesses

Information on request

5 If the Minister determines, in respect of a person that provided information under any of the following provisions, that additional information is necessary to demonstrate that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year, the Minister may request that the person provide him or her with additional information within 60 days after the day on which the request is made:

- **(a)** subparagraph 16(a)(ii) or (b)(ii);
- **(b)** clause 17(b)(i)(B) or (ii)(B);
- **(c)** subparagraph 25(a)(ii) or (b)(ii);
- **(d)** clause 26(b)(i)(B) or (ii)(B);
- **(e)** subparagraph 49(a)(ii) or (b)(ii);
- **(f)** subparagraph 53(a)(ii) or (b)(ii);
- **(g)** subparagraph 57(a)(ii) or (b)(ii);
- **(h)** subparagraph 66(a)(ii) or (b)(ii);
- **(i)** clause 67(b)(i)(B) or (ii)(B);
- **(j)** subparagraph 74(a)(ii) or (b)(ii); or
- **(k)** subparagraph 79(a)(ii) or (b)(ii).

Performance Standard and Remission

Remission — performance standard

6 (1) If the Minister determines that the performance standard has not been met in relation to a fee that is payable under this Order, remission is granted to the person that must pay the fee

- **(a)** of an amount equal to 25% of the fee; or
- **(b)** of an amount equal to 25% of the amount that is payable, in the case where remission is granted of part of the fee under any other provision of this Order.

Exceptions

(2) Subsection (1) does not apply to a fee for the examination of

- **(a)** an application or submission referred to in this Order in respect of which a joint or parallel review is conducted by the Minister and a foreign regulatory authority; or
- **(b)** an application for a licence that is filed under section 32 of the *Medical Devices Regulations* if
  - **(i)** the medical device to which the application relates includes a component that is a drug, and
  - **(ii)** the Minister has made a decision in respect of the application to issue or amend a medical device licence under section 36 of those Regulations, or to refuse to issue or amend such a licence under section 38 of those Regulations.

PART 2

Drugs

DIVISION 1

Fees for Examination of a Submission — Drugs for Human Use

Interpretation

Definition of *submission*

7 In this Division, ***submission*** means any of the following:

- **(a)** an application for a drug identification number that is filed under section C.01.014.1 of the *Food and Drug Regulations*;
- **(b)** a new drug submission that is filed under section C.08.002 of those Regulations;
- **(c)** an abbreviated new drug submission that is filed under section C.08.002.1 of those Regulations; or
- **(d)** a supplement to a new drug submission or abbreviated new drug submission that is filed under section C.08.003 of those Regulations.

Non-application

Non-application

8 This Division does not apply to drugs for veterinary use only.

Fees and Remissions

Fee for examination

9 (1) Subject to paragraph 10(b) and section 12, the fee for the examination of a submission is, in respect of the applicable submission class set out in column 1 of Schedule 1 and described in column 2, as follows:

- **(a)** in the case of a fee that is payable in a fiscal year set out in any of columns 3 to 6 of Schedule 1, the fee set out in that column; and
- **(b)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 3 to 6 of Schedule 1, the amount that is calculated in accordance with subsection 4(2).

Fee paid by person that files submission

(2) The fee is payable by the person that files the submission.

Fee and timing of payment — preliminary examination

10 If a preliminary examination is conducted in respect of a submission,

- **(a)** the full fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 9(2) stating that the submission has been found to be complete and has been accepted for further examination; or
- **(b)** 10% of the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 9(2) stating that the submission has been found to be incomplete.

Fee and timing of payment — no preliminary examination

11 If a preliminary examination is not conducted in respect of a submission, the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 9(2) stating that the submission

has been received.

Fee — filing in previous fiscal year

12 For the purposes of subsection 9(1), if the Minister issues a notice referred to in section 10 or 11 in the fiscal year that follows the fiscal year in which the submission was filed, the fee that is payable is the fee that was payable in the fiscal year in which the submission was filed.

Deferred payment — notice of compliance

13 Despite sections 10 and 11, if the person referred to in subsection 9(2) files an application for authorization under section C.07.003 of the *Food and Drug Regulations* at the same time that the person files the submission, payment of the fee is deferred until the issuance to the person of a notice of compliance under section C.08.004 of those Regulations or of a document setting out the drug identification number assigned for the drug under subsection C.01.014.2(1) of those Regulations.

Remission — urgent public health need

14 Remission is granted to a person referred to in subsection 9(2) that files a new drug submission under section C.08.002 of the *Food and Drug Regulations* or an application for a drug identification number under section C.01.014.1 of those Regulations of the amount of the fee that is payable under subsection 9(1) if, as of the day on which the person filed the new drug submission or application,

- **(a)** the drug has the same medicinal ingredient, strength and route of administration and is in a comparable dosage form as a drug that may be imported under subsection C.10.001(2) of those Regulations;
- **(b)** a drug identification number has not been assigned under subsection C.01.014.2(1) of those Regulations for the drug or for another drug that has the same medicinal ingredient, strength and route of administration and is in a comparable dosage form; and
- **(c)** a notice of compliance has not been issued under section C.08.004 of those Regulations in respect of the drug or another drug that has the same medicinal ingredient, strength and route of administration and is in a comparable dosage form.

Remission — General Council Decision

15 Remission is granted to the person referred to in subsection 9(2) of the amount of the fee that is payable under subsection 9(1) if the person has received an authorization under section 21.04 of the *Patent Act* in respect of the drug.

Remission — small business

16 Subject to section 18, remission is granted to the person referred to in subsection 9(2) of an amount equal to 50% of the fee that is payable under subsection 9(1) if the person provides with their submission, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Remission — first submission by small business

17 Subject to section 18, remission is granted to the person referred to in subsection 9(2) of an amount equal to the fee that is payable under subsection 9(1) if the following conditions are met:

- **(a)** the person has not previously filed a submission in respect of a drug; and
- **(b)** the person provides with their submission, in a form established by the Minister,
  - **(i)** in the case where the person has completed their first fiscal year,
    - **(A)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
    - **(B)** the following information:
      - **(I)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(III)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
      - **(IV)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
  - **(ii)** in the case where the person has not completed their first fiscal year,
    - **(A)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
    - **(B)** the following information:
      - **(I)** a list of the persons with which the person is affiliated in the person's first fiscal year,
      - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
      - **(III)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
      - **(IV)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Fee or difference payable

18 If the Minister requests under section 5 that the person referred to in subsection 9(2) provide additional information, the fee — or the difference between the fee payable under subsection 9(1) and the amount already paid, as the case may be — is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 2

Fees for Examination of a Submission — Drugs for Veterinary Use Only

Interpretation

Definition of *submission*

19 In this Division, ***submission*** means any of the following:

- **(a)** an application for a drug identification number that is filed under section C.01.014.1 of the *Food and Drug Regulations*;
- **(b)** a notification that is filed under subsection C.01.615(1) of those Regulations in respect of a veterinary health product;
- **(c)** a new drug submission that is filed under section C.08.002 of those Regulations;
- **(d)** an abbreviated new drug submission that is filed under section C.08.002.1 of those Regulations;
- **(e)** a supplement to a new drug submission or an abbreviated new drug submission that is filed under section C.08.003 of those Regulations;
- **(f)** a preclinical submission that is filed under subsection C.08.005(1) of those Regulations;
- **(g)** information that is filed under section C.08.010 of those Regulations for the purpose of obtaining a letter of authorization;
- **(h)** information and material that is filed under section C.08.014 of those Regulations for the purpose of obtaining an experimental studies certificate;

- **(i)** information and material that is filed with the Minister in respect of a notifiable change; or
- **(j)** a protocol that is filed with the Minister and may support any of the matters referred to in paragraphs (c) to (f) or (h).

Application

Application

20 This Division applies to drugs for veterinary use only.

Fees and Remissions

Fee for examination

21 (1) Subject to paragraph 22(b) and section 24, the fee that is payable in respect of a submission that is of a type set out in column 1 of Schedule 2, for the examination of each component set out in column 2 that is included in the submission, is as follows:

- **(a)** in the case of a fee that is payable in a fiscal year set out in any of columns 3 to 9 of Schedule 2, the applicable fee set out in that column; and
- **(b)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 3 to 9 of Schedule 2, the amount that is calculated in accordance with subsection 4(2).

Fee paid by person that files submission

(2) The fee is payable by the person that files the submission.

Fee and timing of payment — preliminary examination

22 If a preliminary examination is conducted in respect of a submission,

- **(a)** the full fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 21(2) stating that the submission has been found to be complete and has been accepted for further examination; or
- **(b)** 10% of the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 21(2) stating that the submission has been found to be incomplete.

Fee and timing of payment — no preliminary examination

23 If a preliminary examination is not conducted in respect of a submission, the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 21(2) stating that the submission has been received.

Fee — filing in previous fiscal year

24 For the purposes of subsection 21(1), if the Minister issues a notice referred to in section 22 or 23 in the fiscal year that follows the fiscal year in which the submission was filed, the fee that is payable is the fee that was payable in the fiscal year in which the submission was filed.

Remission — small business

25 Subject to section 27, remission is granted to the person referred to in subsection 21(2) of an amount equal to 50% of the fee that is payable under subsection 21(1) if the person provides with their submission, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,

- **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
- **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
- **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Remission — first submission by small business

26 Subject to section 27, remission is granted to the person referred to in subsection 21(2) of an amount equal to the fee that is payable under subsection 21(1) if the following conditions are met:

- **(a)** the person has not previously filed a submission in respect of a drug; and
- **(b)** the person provides with their submission, in a form established by the Minister,
  - **(i)** in the case where the person has completed their first fiscal year,
    - **(A)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
    - **(B)** the following information:
      - **(I)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(III)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
      - **(IV)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
  - **(ii)** in the case where the person has not completed their first fiscal year,
    - **(A)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
    - **(B)** the following information:
      - **(I)** a list of the persons with which the person is affiliated in the person's first fiscal year,
      - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
      - **(III)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
      - **(IV)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Fee or difference payable

27 If the Minister requests under section 5 that the person referred to in subsection 21(2) provide additional information, the fee — or the difference between the fee payable under subsection 21(1) and the amount already paid, as the case may be — is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 3

Fees for Examination of an Application for an Establishment Licence — Drugs

Interpretation

Definitions

28 The following definitions apply in this Division.

activity means an activity set out in Table I to section C.01A.008 of the *Food and Drug Regulations*. (*activité*)

drug has the same meaning as in subsection C.01A.001(2) of the *Food and Drug Regulations*. (*drogue*)

establishment licence means a licence issued under section C.01A.008 of the *Food and Drug Regulations*. (*licence d'établissement*)

Fees and Remission

Fee for examination

29 (1) Subject to section 48, the fee for the examination of an application for an establishment licence or for the annual review of an establishment licence is the sum of the applicable fees referred to in sections 33 to 40 and the fee payable for the examination of an application to amend an establishment licence to add a building is the sum of the applicable fees referred to in sections 41 to 47.

Fee paid by person that files application

(2) The fee is payable by the person that files the application.

Timing of payment

30 The fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 29(2) stating that the application has been accepted for further examination.

Reinstatement

31 Every provision of this Division that applies to an application for an establishment licence also applies to a request to have such a licence reinstated following the correction of the situation that gave rise to its suspension.

Interpretation

32 In sections 33 to 39, a reference to the examination of an application for an establishment licence includes an examination of an application for the annual review of an establishment licence.

Fee — licence authorizing sterile fabrication

33 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including fabricating drugs in sterile dosage form, the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 1 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 1 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing importation

34 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including importing drugs — but not fabricating drugs in sterile dosage form — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 2 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 2 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing non-sterile fabrication

35 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including fabricating drugs that are not in sterile dosage form — but not fabricating drugs in sterile dosage form or importing drugs — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 3 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 3 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing distribution

36 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including distributing drugs — but not fabricating drugs in sterile dosage form, importing drugs or fabricating drugs that are not in sterile dosage form — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 4 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 4 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing wholesaling

37 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including wholesaling drugs — but not fabricating drugs in sterile dosage form, importing drugs, fabricating drugs that are not in sterile dosage form or distributing drugs — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 5 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 5 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing packaging/labelling

38 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including packaging/labelling drugs — but not fabricating drugs in sterile dosage form, importing drugs, fabricating drugs that are not in sterile dosage form, distributing drugs or wholesaling drugs — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 6 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 6 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — licence authorizing testing

39 For the examination of an application for an establishment licence for each building at which one or more activities are to be conducted, including testing drugs — but not fabricating drugs in sterile dosage form, importing drugs, fabricating drugs that are not in sterile dosage form, distributing drugs, wholesaling drugs or packaging/labelling drugs — the fee is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 7 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 7 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — application for licence — building outside Canada

40 (1) For the examination of an application for an establishment licence referred to in section 33 or 34, the fee for each building located outside Canada that is listed on the application is

- **(a)** in respect of drugs for human use, $918; and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in the fiscal year 2020-2021, $765; and
  - **(ii)** in the case of a fee that is payable in any subsequent fiscal year, $918.

Fee — application for annual review — building outside Canada

(2) For the examination of an application for the annual review of an establishment licence referred to in section 33 or 34, the fee for each building located outside Canada that is listed on the establishment licence is the applicable fee set out in paragraph (1)(a) or (b).

Fee — amendment — licence authorizing sterile fabrication

41 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to fabricate drugs in sterile dosage form at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 1 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 1 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing importation

42 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to import drugs — but not to fabricate drugs in sterile dosage form — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 2 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 2 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing non-sterile fabrication

43 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to fabricate drugs that are not in sterile dosage form — but not to fabricate drugs in sterile dosage form or import drugs — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 3 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2

to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 3 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing distribution

44 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to distribute drugs — but not to fabricate drugs in sterile dosage form, import drugs or fabricate drugs that are not in sterile dosage form — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 4 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 4 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing wholesaling

45 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to wholesale drugs — but not to fabricate drugs in sterile dosage form, import drugs, fabricate drugs that are not in sterile dosage form or distribute drugs — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 5 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 5 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing packaging/labelling

46 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to package/label drugs — but not to fabricate drugs in sterile dosage form, import drugs, fabricate drugs that are not in sterile dosage form, distribute drugs or wholesale drugs — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 6 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 Schedule 3, the amount that is calculated in accordance with subsection 4(2); and
- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 6 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Fee — amendment — licence authorizing testing

47 If an application to amend an establishment licence seeks to add a building and the amendment seeks to authorize the holder to test drugs — but not to fabricate drugs in sterile dosage form, import drugs, fabricate drugs that are not in sterile dosage form, distribute drugs, wholesale drugs or package/label drugs — at that building, the fee for the examination of the application for each building to be added is as follows:

- **(a)** in respect of drugs for human use,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 3, the fee set out in item 7 for that fiscal year, and

- **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 3, the amount that is calculated in accordance with subsection 4(2); and

- **(b)** in respect of drugs for veterinary use only,
  - **(i)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 8 of Schedule 4, the fee set out in item 7 for that fiscal year, and
  - **(ii)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 8 of Schedule 4, the amount that is calculated in accordance with subsection 4(2).

Prorated fee

48 The fee that is payable under subsection 29(1) is reduced by the percentage set out in column 1 of Schedule 5 if the person referred to in subsection 29(2) files, in the period set out in column 2,

- **(a)** an application for an establishment licence and has not previously filed such an application; or
- **(b)** an application to amend an establishment licence that seeks to add a building.

Remission — small business

49 Subject to section 50, remission is granted to the person referred to in subsection 29(2) of an amount equal to 25% of the fee that is payable under subsection 29(1) if the person provides with their application, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Difference payable

50 If the Minister requests under section 5 that the person referred to in subsection 29(2) provide additional information, the difference between the fee payable under subsection 29(1) and the amount already paid is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 4

Fees for Right to Sell Drugs for Human Use

Non-application

Non-application

51 This Division does not apply to drugs for veterinary use only.

Fees and Remission

Annual fee

52 (1) The annual fee that is payable for the right to sell a drug for which a drug identification number has been assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations* is, in respect of the type of drug set out in column 1 of Schedule 6, as follows:

- **(a)** in the case of a fee that is payable in a fiscal year set out in any of columns 2 to 5 of Schedule 6, the fee set out in that column; and
- **(b)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 2 to 5 of Schedule 6, the amount that is calculated in accordance with subsection 4(2).

Fee payable by person after first sale

(2) The fee is payable by the person to which a document was issued under subsection C.01.014.2(1) of the *Food and Drug Regulations* that sets out the drug identification number assigned for the drug if the person has sold the drug following the issuance of the document.

Timing of payment

(3) The fee is payable on October 1.

Non-application — interruption of sale

(4) Subject to subsection (5), subsection (1) does not apply to the person if they notified the Minister in accordance with section C.01.014.71 of the *Food and Drug Regulations* in the 12 months preceding October 1.

Resumption of sale

(5) Subsection (4) ceases to apply on the day on which the person notifies the Minister in accordance with section C.01.014.72 of the *Food and Drug Regulations*.

Remission — small business

53 Subject to section 54, remission is granted to the person referred to in subsection 52(2) of an amount equal to 25% of the fee that is payable under subsection 52(1) if the person provides with the notification provided under subsection C.01.014.5(1) of the *Food and Drug Regulations*, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Difference payable

54 If the Minister requests under section 5 that the person referred to in subsection 52(2) provide additional information, the difference between the fee payable under subsection 52(1) and the amount already paid is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 5

Fees for Right to Sell Drugs for Veterinary Use Only

Application

Application

55 This Division applies to drug for veterinary use only.

Fees and Remission

Annual fee

56 (1) The annual fee that is payable for the right to sell a drug for which a drug identification number has been assigned under subsection C.01.014.2(1) of the *Food and Drug Regulations* is as follows:

- **(a)** in the case of a fee that is payable in a fiscal year set out in any of columns 1 to 4 of Schedule 7, the fee set out in that column; and
- **(b)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 1 to 4 of Schedule 7, the amount that is calculated in accordance with subsection 4(2).

Fee payable by person after first sale

(2) The fee is payable by the person to which a document was issued under subsection C.01.014.2(1) of the *Food and Drug Regulations* that sets out the drug identification number assigned for the drug if the person has sold the drug following the issuance of the document.

Timing of payment

(3) The fee is payable on October 1.

Non-application — interruption of sale

(4) Subject to subsection (5), subsection (1) does not apply to the person if they notified the Minister in accordance with section C.01.014.71 of the *Food and Drug Regulations* in the 12 months preceding October 1.

Resumption of sale

(5) Subsection (4) ceases to apply on the day on which the person notifies the Minister in accordance with section C.01.014.72 of the *Food and Drug Regulations*.

Remission — small business

57 Subject to section 58, remission is granted to the person referred to in subsection 56(2) of an amount equal to 25% of the fee that is payable under subsection 56(1) if the person provides with the notification provided under subsection C.01.014.5(1) of the *Food and Drug Regulations*, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,

- **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
- **(ii)** the following information:
  - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
  - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
  - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
  - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Difference payable

58 If the Minister requests under section 5 that the person referred to in subsection 56(2) provide additional information, the difference between the fee payable under subsection 56(1) and the amount already paid is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

PART 3

Medical Devices

DIVISION 1

Fees for Examination of an Application for a Medical Device Licence

Interpretation

Definition of *licence*

59 In this Division, ***licence*** means a medical device licence issued under paragraph 36(1)(a) of the *Medical Devices Regulations*.

Fees and Remissions

Fee for examination

60 (1) Subject to paragraph 62(b) and section 64, the fee for the examination of an application for a licence that is filed under section 32 of the *Medical Devices Regulations* or for the examination of an application for a licence amendment that is filed under section 34 of those Regulations is, in respect of the applicable category set out in column 1 of Schedule 8 and described in column 2, as follows:

- **(a)** in the case of a fee that is payable in a fiscal year set out in any of columns 3 to 6 of Schedule 8, the fee set out in that column; and
- **(b)** in the case of a fee that is payable in a fiscal year other than one set out in any of columns 3 to 6 of Schedule 8, the amount that is calculated in accordance with subsection 4(2).

Fee payable by person that files application

(2) The fee is payable by the person that files the application.

Reinstatement

61 Every provision of this Division that applies to an application for a licence for a Class II, III or IV medical device filed under section 32 of the *Medical Devices Regulations* also applies to a request to have such a licence reinstated following the correction of the situation that gave rise to its suspension.

Fee and timing of payment — preliminary examination

62 If a preliminary examination is conducted in respect of an application,

- **(a)** the full fee is payable on the issuance by the Minister of a notice to the person referred to in

subsection 60(2) stating that the application has been found to be complete and has been accepted for further examination; or
- **(b)** 10% of the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 60(2) stating that the application has been found to be incomplete.

Fee and timing of payment — no preliminary examination

63 If a preliminary examination is not conducted in respect of an application, the fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 60(2) stating that the application has been received.

Fee — filing in previous fiscal year

64 For the purposes of subsection 60(1), if the Minister issues a notice referred to in section 62 or 63 in the fiscal year that follows the fiscal year in which the application was filed, the fee that is payable is the fee that was payable in the fiscal year in which the application was filed.

Remission — General Council Decision

65 Remission is granted to the person referred to in subsection 60(2) of an amount equal to the fee that is payable under subsection 60(1) if the person has received an authorization under section 21.04 of the *Patent Act* in respect of the medical device.

Remission — small business

66 Subject to section 68, remission is granted to the person referred to in subsection 60(2) of an amount equal to 50% of the fee that is payable under subsection 60(1) if the person provides with their application, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Remission — first application by small business

67 Subject to section 68, remission is granted to the person referred to in subsection 60(2) of an amount equal to the fee that is payable under subsection 60(1) if the following conditions are met:

- **(a)** the person has not previously filed an application for a licence under section 32 of the *Medical Devices Regulations*; and
- **(b)** the person provides with their application, in a form established by the Minister,
  - **(i)** in the case where the person has completed their first fiscal year,
    - **(A)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
    - **(B)** the following information:
      - **(I)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
      - **(III)** the number of employees of the person in their last fiscal year and of the

persons with which the person was affiliated in those persons' last completed fiscal year, and
- **(IV)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and

- **(ii)** in the case where the person has not completed their first fiscal year,
  - **(A)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(B)** the following information:
    - **(I)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(II)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(III)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(IV)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Fee or difference payable

68 If the Minister requests under section 5 that the person referred to in subsection 60(2) provide additional information, the fee — or the difference between the fee payable under subsection 60(1) and the amount already paid, as the case may be — is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 2

Fees for Examination of an Application for an Establishment Licence — Medical Devices

Interpretation

Definition of *establishment licence*

69 In this Division, ***establishment licence*** means a licence issued under section 46 of the *Medical Devices Regulations*.

Application

Applicable classes

70 This Division applies to persons that import or sell medical devices that are subject to the *Medical Devices Regulations*, other than persons that import or sell only medical devices that are subject to Part 2 or 3 of those Regulations.

Fee and Remission

Fee for examination

71 (1) The fee that is payable for the examination of an application for an establishment licence filed under section 45 of the *Medical Devices Regulations* or for the annual review of such a licence filed under section 46.1 of those Regulations is $4,590.

Fee paid by person that files application

(2) The fee is payable by the person that files the application.

Timing of payment

72 The fee is payable on the issuance by the Minister of a notice to the person referred to in subsection 71(2) stating that the application has been accepted for further examination.

Reinstatement

73 Every provision of this Division that applies to an application for an establishment licence also applies to a request to have such a licence reinstated following the correction of the situation that gave rise to its suspension.

Remission — small business

74 Subject to section 75, remission is granted to the person referred to in subsection 71(2) of an amount equal to 25% of the fee that is payable under subsection 71(1) if the person provides with their application, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Difference payable

75 If the Minister requests under section 5 that the person referred to in subsection 71(2) provide additional information, the difference between the fee payable under subsection 71(1) and the amount already paid is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

DIVISION 3

Fees for Right to Sell Licensed Class II, III or IV Medical Devices

Interpretation

Definition of *licence*

76 In this Division, ***licence*** means a medical device licence issued under paragraph 36(1)(a) of the *Medical Devices Regulations*.

Fees and Remission

Annual fee

77 (1) The annual fee that is payable for the right to sell a licensed Class II, III or IV medical device is $381.

Fee payable by holder — licence not suspended

(2) The fee is payable by the person that holds the licence for the Class II, III or IV medical device if the licence is not suspended under section 40 or 41 of the *Medical Devices Regulations*.

Timing of payment

78 The fee is payable on December 20.

Remission — small business

79 Subject to section 80, remission is granted to the person referred to in subsection 77(2) of an amount equal to 25% of the fee that is payable under subsection 77(1) if the person provides with the statement provided under subsection 43(1) of the *Medical Devices Regulations*, in a form established by the Minister,

- **(a)** in the case where the person has completed their first fiscal year,
  - **(i)** a statement indicating that the person met the definition *small business* in subsection 1(1) in their last completed fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person was affiliated in the person's last completed fiscal year,
    - **(C)** the number of employees of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year, and
    - **(D)** the gross revenue of the person in their last fiscal year and of the persons with which the person was affiliated in those persons' last completed fiscal year; and
- **(b)** in the case where the person has not completed their first fiscal year,
  - **(i)** a statement indicating that the person anticipates meeting the definition *small business* in subsection 1(1) in their first fiscal year, and
  - **(ii)** the following information:
    - **(A)** a list of the persons with which the person is affiliated in the person's first fiscal year,
    - **(B)** the start and end dates of the person's fiscal year and of the fiscal year of the persons with which the person is affiliated in the person's first fiscal year,
    - **(C)** the number of employees of the person in their first fiscal year and of the persons with which the person is affiliated in those persons' last completed fiscal year, and
    - **(D)** the projected gross revenue of the person in their first fiscal year and the gross revenue of the persons with which the person is affiliated in those persons' last completed fiscal year.

Difference payable

80 If the Minister requests under section 5 that the person referred to in subsection 77(2) provide additional information, the difference between the fee payable under subsection 77(1) and the amount already paid is immediately payable if

- **(a)** the person has not provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition *small business* in subsection 1(1) in the applicable fiscal year; or
- **(b)** the person has provided, within the period specified in section 5, the Minister with additional information for the purpose of demonstrating that the person met the definition in the applicable fiscal year but the Minister determines, after the period ends, that the person has not provided sufficient information to demonstrate that they met that definition in the applicable fiscal year.

Coming into Force

SOR/96-143

81 This Order comes into force on the day on which the *Veterinary Drug Evaluation Fees Regulations* are repealed but if it is registered after that day, it comes into force on the day on which it is registered.

SCHEDULE 1

(Section 9)

Fees for Examination of a Submission — Drugs for Human Use

Item	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Submission Class	Description	Fee ($) Fiscal Year 2020-2021	Fee ($) Fiscal Year 2021-2022	Fee ($) Fiscal Year 2022-2023	Fee ($) Fiscal Year 2023-2024

1	New active substance	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph	400,288	437,884	475,481	513,077
2	Clinical or non-clinical data and chemistry and manufacturing data	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance	204,197	224,691	245,185	265,678
3	Clinical or non-clinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance	90,864	95,987	101,110	106,232
4	Comparative studies	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance	53,836	55,848	57,859	59,870
5	Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance	27,587	30,670	33,752	36,835
6	Clinical or non-clinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance	19,442	19,442	19,442	19,442
7	Labelling only	Submissions, other than those described in item 8, 11 or 12, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability or applications for a drug identification number in support of changes to brand names of non-	3,816	4,328	4,841	5,353

		prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data)				
8	Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment	2,010	2,010	2,010	2,010
9	Administrative submission	Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the *Food and Drugs Act*)	432	540	676	845
10	Disinfectant — full review	Submissions, other than those described in item 11, that include data in support of a disinfectant	5,712	7,140	8,925	11,157
11	Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacturer's name or brand name that requires a review of labelling material due to deviations from the previously authorized	2,507	2,507	2,507	2,507

		labelling or drug				
12	Drug identification number application — labelling standards	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug and that do not include clinical or non-clinical data or chemistry and manufacturing data	1,616	1,616	1,616	1,616

SCHEDULE 2

(Section 21)

Fees for Examination of a Submission — Drugs for Veterinary Use Only

Item	Column 1 Type of Submission	Column 2 Component	Column 3 Fee ($) Fiscal Year 2020-2021	Column 4 Fee ($) Fiscal Year 2021-2022	Column 5 Fee ($) Fiscal Year 2022-2023	Column 6 Fee ($) Fiscal Year 2023-2024	Colum Fee (Fisc Yea 2024-2
1	Application for drug identification number	Information, other than that referred to in item 2, to support an application for a drug identification number, including the submission of labelling material for a second review, if required	918	1,148	1,436	1,714	1,959
2	Application for drug identification number	Published references or other data	638	798	998	1,191	1,361
3	Application for drug identification number	Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug table 2 note 1	320	400	500	596	681
4	Notification — veterinary health product	Information contained in a notification filed under subsection C.01.615(1) of the *Food and Drug Regulations* in respect of a veterinary health product	486	486	486	486	486
5	New drug submission	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species (in the case of an	20,375	25,469	31,837	38,033	43,467

		antiparasitic drug, several indications in one food animal species)					
6	New drug submission	Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	12,342	15,428	19,286	23,039	26,331
7	New drug submission	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species	29,631	37,040	46,300	55,312	63,214
8	New drug submission	Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	40,125	50,157	62,697	74,899	85,599
9	New drug submission	Comparative (pharmacodynamic, clinical or bioavailability) data to support an additional route of administration	3,698	4,623	5,779	6,903	7,889
10	New drug submission	Comparative (pharmacodynamic, clinical or bioavailability) data to support each additional strength	612	765	957	1,143	1,306
11	New drug submission	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	27,783	34,729	43,412	51,861	59,270
12	New drug submission	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety	37,040	46,300	57,875	69,140	79,017

		factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species					
13	New drug submission	For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	3,698	4,623	5,779	6,903	7,889
14	New drug submission	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in an additional species	18,513	23,142	28,928	34,558	39,495
15	New drug submission	Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	6,171	7,715	9,644	11,520	13,166
16	New drug submission	Chemistry and manufacturing data to support one strength of a single dosage form	6,171	7,715	9,644	11,520	13,166
17	New drug submission	Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 16	3,086	3,858	4,823	5,760	6,584
18	New drug submission	Documentation to support a change of manufacturer table 2 note 2	320	400	500	596	681
19	Supplement to a new drug submission	Efficacy data to support an additional indication in one animal species	16,053	20,067	25,084	29,965	34,246
20	Supplement to a new drug submission	Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	12,342	15,428	19,286	23,039	26,331

21	Supplement to a new drug submission	Efficacy and safety data (in the intended species) to support an indication in another animal species	20,375	25,469	31,837	38,033	43,467
22	Supplement to a new drug submission	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species	29,631	37,040	46,300	55,312	63,214
23	Supplement to a new drug submission	Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	40,125	50,157	62,697	74,899	85,599
24	Supplement to a new drug submission	Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	9,869	12,336	15,421	18,422	21,053
25	Supplement to a new drug submission	Comparative (pharmacodynamic, clinical or bioavailability) data to support an additional route of administration	3,698	4,623	5,779	6,903	7,889
26	Supplement to a new drug submission	Comparative (pharmacodynamic, clinical or bioavailability) data to support each additional strength	612	765	957	1,143	1,306
27	Supplement to a new drug submission	For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species	3,698	4,623	5,779	6,903	7,889
28	Supplement to a new drug submission	For food-producing animals, metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage and route of administration of an approved dosage form in an additional species	18,513	23,142	28,928	34,558	39,495

29	Supplement to a new drug submission	For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, a maximum residue limit and a withdrawal period	9,257	11,571	14,464	17,279	19,748
30	Supplement to a new drug submission	For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required	7,409	9,261	11,576	13,829	15,804
31	Supplement to a new drug submission	Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	6,171	7,715	9,644	11,520	13,166
32	Supplement to a new drug submission	Chemistry and manufacturing data to support a change in formulation or dosage form	3,086	3,858	4,823	5,760	6,584
33	Supplement to a new drug submission	Chemistry and manufacturing data to support a change in the packaging or sterilization process	2,462	3,078	3,848	4,595	5,250
34	Supplement to a new drug submission	Chemistry and manufacturing data to support an extension of the expiry date	1,850	2,313	2,891	3,452	3,945
35	Supplement to a new drug submission	Chemistry and manufacturing data to support the concurrent use of two drugs	1,850	2,313	2,891	3,452	3,945
36	Supplement to a new drug submission	Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage form	612	765	957	1,143	1,306
37	Supplement to a new drug submission	Documentation to support a change to the brand name of a drug table 2 note 3	320	400	500	596	681
38	Abbreviated new drug submission or supplement to an abbreviated new drug submission	Comparative (pharmacodynamic, clinical or bioavailability) data to support a single route of administration and dosage form	3,698	4,623	5,779	6,903	7,889
39	Abbreviated new drug submission or supplement to an abbreviated new drug submission	For food-producing animals, residue depletion studies to confirm that the withdrawal periods for each species fall	3,698	4,623	5,779	6,903	7,889

		within the conditions of use for the Canadian reference product					
40	Abbreviated new drug submission or supplement to an abbreviated new drug submission	Chemistry and manufacturing data for a non-compendial medicinal ingredient of a drug	6,171	7,715	9,644	11,520	13,166
41	Abbreviated new drug submission or supplement to an abbreviated new drug submission	Chemistry and manufacturing data to support a single dosage form	6,171	7,715	9,644	11,520	13,166
42	Abbreviated new drug submission or supplement to an abbreviated new drug submission	Documentation to support • **(a)** a change of manufacturer, in the case of an abbreviated new drug submission; or • **(b)** a change to the brand name of a drug, in the case of a supplement to an abbreviated new drug submission table 2 note 4	320	400	500	596	681
43	Preclinical submission	Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dosage form, route of administration and indication in one species	6,171	7,715	9,644	11,520	13,166
44	Preclinical submission	Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated	4,935	6,169	7,712	9,211	10,527
45	Preclinical submission	For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one	18,513	23,142	28,928	34,558	39,495

		species					
46	Preclinical submission	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	27,783	34,729	43,412	51,861	59,270
47	Preclinical submission	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	37,040	46,300	57,875	69,140	79,017
48	Preclinical submission	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species	9,257	11,571	14,464	17,279	19,748
49	Preclinical submission	Chemistry and manufacturing data to support a single dosage form containing a non-compendial medicinal ingredient	6,171	7,715	9,644	11,520	13,166
50	Preclinical submission	Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	3,086	3,858	4,823	5,760	6,584
51	Sale of new drug for emergency treatment	Information and material to support the sale of a new drug to be used in the emergency treatment of a non-food-producing animal	51	51	51	51	51
52	Sale of new drug for emergency treatment	Information and material to support the sale of a new drug	102	102	102	102	102

		to be used in the emergency treatment of a food-producing animal					
53	Experimental studies certificate	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal	980	980	980	980	980
54	Experimental studies certificate	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that of a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal	490	490	490	490	490
55	Experimental studies certificate	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal	2,958	2,958	2,958	2,958	2,958
56	Experimental studies certificate	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that of a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal	490	490	490	490	490
57	Notifiable change	Information and material to support an application for a notifiable change	1,658	2,073	2,591	3,095	3,537
58	Protocol	A protocol that is filed with the Minister and may support a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or abbreviated new drug submission, a preclinical submission or information and material that is filed for the purpose of obtaining an experimental studies certificate	1,658	2,073	2,591	3,095	3,537

Table 2 note(s)

Table 2 Note 1

This item applies only to an application for a drug identification number that does not include either of the co and 2.

Return to table 2 note 1 referrer

Table 2 Note 2

This item applies only to a new drug submission that does not include any of the components set out in items

Return to table 2 note 2 referrer

Table 2 Note 3

This item applies only to a supplement to a new drug submission that does not include any of the components

Return to table 2 note 3 referrer

Table 2 Note 4

This item applies only to an abbreviated new drug submission or a supplement to an abbreviated new drug su any of the components set out in items 38 to 41.

Return to table 2 note 4 referrer

SCHEDULE 3

(Sections 33 to 39 and 41 to 47)

Fees for Examination of an Application for an Establishment Licence — Drugs for Human Use

Item	Column 1 Activity	Column 2 Fee ($) Fiscal Year 2020-2021	Column 3 Fee ($) Fiscal Year 2021-2022	Column 4 Fee ($) Fiscal Year 2022-2023	Column 5 Fee ($) Fiscal Year 2023-2024
1	Fabrication — sterile dosage form	41,626	41,730	41,834	41,937
2	Importation	27,359	29,033	30,707	32,380
3	Fabrication — non-sterile dosage form	27,000	28,364	29,727	31,091
4	Distribution	12,560	13,882	15,205	16,527
5	Wholesaling	4,937	6,171	7,715	9,644
6	Packaging/labelling	6,061	6,061	6,061	6,061
7	Testing	2,560	3,200	4,001	5,002

SCHEDULE 4

(Sections 33 to 39 and 41 to 47)

Fees for Examination of an Application for an Establishment Licence — Drugs for Veterinary Use Only

Item	Column 1 Activity	Column 2 Fee ($) Fiscal Year 2020-2021	Column 3 Fee ($) Fiscal Year 2021-2022	Column 4 Fee ($) Fiscal Year 2022-2023	Column 5 Fee ($) Fiscal Year 2023-2024	Column 6 Fee ($) Fiscal Year 2024-2025	Column 7 Fee ($) Fiscal Year 2025-2026	Column Fee ($ Fiscal Year 2026-2(

1	Fabrication — sterile dosage form	40,198	40,487	40,777	41,068	41,357	41,647	41,937
2	Importation	10,715	13,393	16,742	20,927	26,158	32,380	32,380
3	Fabrication — non-sterile dosage form	8,782	10,978	13,722	17,152	21,440	26,800	31,091
4	Distribution	4,835	6,043	7,555	9,443	11,803	14,754	16,527
5	Wholesaling	1,933	2,416	3,020	3,774	4,718	5,898	7,372
6	Packaging/labelling	6,061	6,061	6,061	6,061	6,061	6,061	6,061
7	Testing	1,315	1,644	2,055	2,569	3,210	4,013	5,002

SCHEDULE 5

(Section 48)

Fee Reduction — Application for an Establishment Licence — Drugs

Item	Column 1 Percentage of Fee Reduction	Column 2 Filing Period
1	25%	July 1 to September 30
2	50%	October 1 to December 31
3	75%	January 1 to March 31

Note: The fee payable under subsection 30(1) of this Order is not reduced if an application is filed on or after April 1 and up to and including June 30.

SCHEDULE 6

(Section 52)

Fees for Right to Sell Drugs for Human Use

Interpretation

Definition of *disinfectant*

1 In this Schedule, ***disinfectant*** has the meaning assigned by the definition *antimicrobial agent* in subsection C.01A.001(1) of the *Food and Drug Regulations*.

Item	Column 1 Type of Drug	Column 2 Fee ($) Fiscal Year 2020-2021	Column 3 Fee ($) Fiscal Year 2021-2022	Column 4 Fee ($) Fiscal Year 2022-2023	Column 5 Fee ($) Fiscal Year 2023-2024
1	Disinfectant	1,285	1,344	1,403	1,462
2	Non-prescription drug	1,623	2,022	2,421	2,820
3	Drug other than one referred to in item 1 or 2	1,836	2,754	4,080	4,679

SCHEDULE 7

(Section 56)

Fees for Right to Sell Drugs for Veterinary Use Only

Item	Column 1 Fee ($) Fiscal Year 2020-2021	Column 2 Fee ($) Fiscal Year 2021-2022	Column 3 Fee ($) Fiscal Year 2022-2023	Column 4 Fee ($) Fiscal Year 2023-2024
1	312	367	422	477

SCHEDULE 8

(Section 60)

Fees for Examination of an Application for a Medical Device Licence

Interpretation

Definition of *private label medical device*

1 In this Schedule, ***private label medical device*** means a medical device that is identical in every respect to a medical device in respect of which a licence has been issued, except that the device is labelled with the name and address of another manufacturer and the name and identifier of the device that the other manufacturer is proposing to sell under its own name or under a trademark, design, trade-name or other name or mark owned or controlled by it.

Item	Column 1 Category	Column 2 Description	Column 3 Fee ($) Fiscal Year 2020-2021	Column 4 Fee ($) Fiscal Year 2021-2022	Column 5 Fee ($) Fiscal Year 2022-2023	Column 6 Fee ($) Fiscal Year 2023-2024
1	Applications for Class II licence	Applications for Class II medical device licence other than those referred to in item 10	450	478	505	533
2	Applications for Class II licence amendment	Applications for amendment of Class II medical device licence other than those referred to in item 10	272	272	272	272
3	Applications for Class III licence	Applications for Class III medical device licence other than those referred to in item 4 or 10	7,477	8,912	10,347	11,783
4	Applications for Class III licence (near patient)	Applications for Class III medical device licence for a near patient in vitro diagnostic device	12,851	16,064	20,081	25,102
5	Applications for Class III licence amendment — changes in manufacturing	Applications for amendment of Class III medical device licence — changes in manufacturing process, facility or equipment or manufacturing quality control procedures	1,903	2,379	2,974	3,717
6	Applications for Class III licence amendment — significant changes not related to manufacturing	Applications for amendment of Class III medical device licence — significant changes other than those referred to in item 5	6,608	7,558	8,508	9,458
7	Applications for Class IV licence	Applications for Class IV medical device licence other than those referred to in item 10	24,345	24,748	25,151	25,554
8	Applications for Class IV licence amendment — changes in manufacturing	Applications for amendment of Class IV medical device licence — changes	1,903	2,379	2,974	3,717

		referred to in paragraph 34(a) of the *Medical Devices Regulations* that relate to manufacturing				
9	Applications for Class IV licence amendment — significant changes not related to manufacturing	Applications for amendment of Class IV medical device licence — any other changes referred to in paragraph 34(a) or (b) of the *Medical Devices Regulations*	8,057	9,983	11,752	13,521
10	Applications for Class II, III or Class IV licence or licence amendment — private label medical device	Applications for Class II, III or IV medical device licence or applications for amendment of such a licence — private label medical device	147	147	147	147

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order*.)

Issues

Health Canada (the Department) has responsibility in Canada to regulate the safety, efficacy and quality of health products. The Department charges fees for certain services and activities related to the regulation of health products (including pharmaceutical and biologic drugs, medical devices and veterinary drugs) under the *Financial Administration Act* (FAA). These fees apply to activities such as pre-market regulatory review, the ongoing surveillance of products once they are on the market, and the review of establishment licences.

Health Canada last updated its fees relating to human drugs and medical devices in 2011. Fees for veterinary drugs were enacted in stages between 1995 and 1998 and have not been updated since their inception. Prior to the *Food and Drugs Act* (FDA) amendments in 2017, fees relating to therapeutic products that were enacted under the FDA could only be changed through a regulation made by the Governor in Council and had to meet the requirements found under the former *User Fees Act*. This process took several years, which resulted in Health Canada's fees for services and activities related to drugs (human and veterinary) and medical devices not being up to date with evolving regulatory costs. As a consequence, Health Canada's fees in relation to drugs and medical devices no longer reflect current costs to the Department, nor are they well aligned with fees charged by regulatory partners.

Background

Amendments to the FDA were made through the *Budget Implementation Act, 2017, No. 1* (BIA 1), and gave the Minister of Health (the Minister) authority under subsection 30.61(1) of the FDA to fix, by order, fees for services, regulatory processes or approvals, products, rights and privileges provided under the FDA. It also gave the Minister authority to remit those fees, to adjust them and to withhold or withdraw services for the non-payment of fees. Furthermore, amendments to the FDA exempt those fees from the requirements of the *Service Fees Act* (formerly the *User Fees Act*).

These authorities provide the Minister with levers to set or update fees efficiently. By being able to fix fees by ministerial order under the FDA, the Minister has the flexibility to set and adjust fees in a timely way so that they better reflect actual costs. A modernized cost recovery regime will ensure that industry pays an appropriate share of the costs associated with regulating health products in Canada, while alleviating some of the costs of regulatory services for taxpayers.

In order to implement the new fee regime, several of the current fee regulations under the FAA will be repealed, while some will be amended in part, by way of the *Regulations Amending and Repealing Certain Regulations Made under the Financial Administration Act*. The *Fees in Respect of Drugs and Medical Devices Regulations* under the FAA will in large part be repealed, as well as amended. The *Veterinary Drug Evaluation Fees Regulations*, the *Establishment Licensing Fees (Veterinary Drugs) Regulations* and the *Authority to Sell Veterinary Drugs Fees Regulations* will be repealed. Transitional provisions will also be made so that fee deferrals and remissions pending at the time of the repeal will be allowed to continue.

Objective

The *Fees in Respect of Drugs and Medical Devices Order* (the ministerial order) will revise the fee structure and cost recovery framework for drugs and medical devices. A modernized cost recovery framework supports effective and responsive service delivery, a fair and consistent approach to program funding, while at the same time alleviating the costs of regulatory services on Canadian taxpayers.

Description

The ministerial order will fix fees in relation to human drugs, veterinary drugs and medical devices for pre- and post-market activities under the *Food and Drug Regulations* (FDR) and under the *Medical Devices Regulations* (MDR), in respect of

- the examination of an application for a drug identification number, the examination of a new drug submission, an abbreviated new drug submission, or a supplement to a new drug submission or an abbreviated new drug submission;
- the examination of a veterinary health product notification, or a veterinary drug preclinical submission;
- the examination of information filed for the purpose of obtaining a veterinary drug emergency release application (letter of authorization under section C.08.010 of the FDR), any information and material in respect of a veterinary drug protocol, a notifiable change, or a veterinary drug experimental studies certificate;
- the examination of an application for a drug establishment licence, an amendment to add a new building to the licence or the annual review of the licence;
- the right to sell a drug;
- the examination of an application for a medical device licence;
- the examination of an application for a medical device establishment licence or the annual review of the licence; and
- the right to sell a medical device.

Fee setting

All fees described below have been fixed based on the costs of delivering the regulatory service or program.

Pre-market evaluation and review fees

- Fees were fixed at 75% of regulatory costs for the pre-market review of applications and submissions relating to human drugs and medical device licences. For any fee line increasing from the current fee levels, the fee is phased in over four years. Fees that are decreasing from current levels and all new fee categories are being implemented in the first year (i.e. no phase-in of fees).
- Fees were fixed at 50% of regulatory costs for the pre-market review of veterinary drug submissions. These fees will be phased in over seven years.

Establishment licence fees

- Fees were fixed at 100% of regulatory costs for the examination of an application for a drug establishment licence (DEL), an application to add a building to the DEL, all buildings outside Canada listed on the DEL and the annual review of the DEL. These fees are phased in over four years for human drug establishments and seven years for veterinary drug only establishments.
- Establishment licence holders dealing with both veterinary drug and human drug products at the same establishment will be charged the human drug DEL fee, given that the human drug fee is more reflective of the cost of oversight.
- For all drugs, the DEL fee will be calculated based on the highest risk (most upstream) activity conducted at each domestic building listed on the DEL. In addition, the DEL fee will include a flat fee for each building located outside Canada that is listed on the DEL.
- Fees were fixed at 100% of regulatory costs for the examination of an application and the annual review of a medical device establishment licence (MDEL). Since the MDEL fee will be decreased from the current fee to reflect updated costs, there will not be a phase-in period for this fee line.

Fees for right to sell

- Fees were fixed at 67% of post-market regulatory costs for the right to sell human drugs and veterinary drugs. The fee for right to sell is split into the following three tiers for human drugs: disinfectant; non-prescription drug; and any other drug. The fee for right to sell will be phased in over four years for human and veterinary drugs.
- Products that have been identified as dormant will not be charged a fee for right to sell. However, in cases where the drug becomes dormant during the year, the fee for right to sell will not be remitted.
- Fees were fixed at 67% of post-market regulatory costs for the right to sell licensed medical devices. Since this fee will be decreased from the current fee to reflect updated costs, there will not be a

phase-in period for this fee line.

Exemptions

The following will be exempt from the payment of fees:

- drugs that are the subject of an extraordinary use new drug submission (EUNDS) or an abbreviated extraordinary use new drug submission (AEUNDS);
- publicly funded health care institutions; and
- branches or agencies of the Government of Canada or of the government of a province.

Annual fee adjustment

Every fee payable under the ministerial order will be adjusted annually on April 1st, beginning on April 1, 2021, by the consumer price index (CPI). To further clarify, all the fees set out in the ministerial order, including those in the schedules, will change over time as cumulative CPI adjustments are made to the fees in each fiscal year.

Mitigation measures

In order to qualify for mitigation measures for small businesses, a person (company or individual) must meet one of two criteria:

- the total number of the person's employees (including those of the person's affiliates) must be fewer than 100; or
- the person's total annual gross revenue (including that of the person's affiliates) is between $30,000 and $5 million.

For small businesses that can demonstrate one of the above criteria for their last completed fiscal year, the ministerial order establishes the following mitigation measures:

- a full remission for a first pre-market submission or application;
- a 50% remission for all pre-market evaluation fees;
- a 25% remission for all fees for right to sell; and
- a 25% remission for all establishment licence fees.

Where a small business does not have a completed previous fiscal year, it must demonstrate that it meets one of the above-mentioned criteria in its current/first fiscal year (taking into account the number of employees or annual gross revenues of any affiliates in their last completed fiscal year).

A remission will also be possible for the full amount of the fee payable for the examination of a new drug submission or for the examination of an application for a drug identification number if the submission or application relates to a drug that may be imported under subsection C.10.001(2) of the *Food and Drug Regulations* for an urgent public health need. The remission will be granted if the drug, which must have a comparable dosage form, also has the same medicinal ingredient, strength and route of administration as the drug that may be imported under subsection C.10.001(2). No such drug, however, must already be approved for sale or have a drug identification number assigned to it.

The current remission granted to human drug or device manufacturers who have received an authorization in relation to a General Council Decision under section 21.04 of the *Patent Act* (i.e. Canada Access to Medicine Regime) is continued under this ministerial order.

With regard to the drug establishment licence fees, new applicants and applicants for amendments to add a new building to a DEL will have their fees prorated for a portion of the Government of Canada fiscal year in which they apply.

Performance standards and remission

All Health Canada fees will have appropriate performance standards that reflect the Department's ability to deliver its service(s) within a set time frame. These standards will be used to assess performance for the purpose of calculating the performance standard remissions and will be outlined in detail in a document entitled *Performance Standards for the Fees in Respect of Drugs and Medical Devices Order*. This document was published by the Government of Canada and dated November 22, 2018. In a case where an applicable performance standard has not been met, the Minister will be required to remit 25% of the applicable fee. Performance standards are incorporated by reference into the ministerial order using the authorities under the *Statutory Instruments Act*.

Health Canada joint and parallel reviews with other regulatory agencies will be exempt from the application of the performance standard remissions. Medical device combination reviews where the medical device includes a drug component and a decision has been made to issue or amend (or refuse to

issue or amend) a medical device licence will also be exempt from the application of performance standard remissions.

Remissions for missed performance standards will also apply in a case where the person has already received a small business remission. For example, in cases where a company receives a remission of 50% as a result of a small business remission, the performance standard remission would be 25% of the remaining 50% of the fee payable.

Coming into force

The ministerial order will come into force on the day on which the *Veterinary Drug Evaluation Fees Regulations* are repealed, unless it is registered at a later date. The repeal of those Regulations comes into force on April 1, 2020.

Rationale

The ministerial order is aligned with the Government's recent commitments on fees in Budget 2017. Establishing a new cost recovery framework ensures fairness for Canadian taxpayers by supporting a better balance between tax-based funding and fees where there is a private benefit. Revenues from fees assist Health Canada to continue to meet its internationally aligned performance standards, in turn supporting timely access to drugs and medical devices, thus benefiting consumers and industry.

In the spirit of regulatory cooperation, the new cost recovery framework aims to align with the rules of Canada's key trading partners to the greatest extent possible. A modern and internationally comparable cost recovery system will alleviate pressure on a strained system and support Health Canada in maintaining performance standards in a manner that is fair to taxpayers. Some comparable regulators in the G-20 currently charge 100% of regulatory costs to industry, while Health Canada only charges 43%. Fee setting via a ministerial order should help Health Canada keep up to date on adjusting fees to reflect regulatory costs.

Accountability principles are preserved under the new fee regime. The FDA requires that the Minister consult stakeholders prior to fixing fees. Under the FDA, a fee fixed for a service may not exceed the cost to Government of providing the service. The new fee regime maintains a financial accountability for missed performance standards by remitting fees under the new authorities. The new cost recovery regime also continues to include fee mitigation measures and introduces an annual adjustment of fees in accordance with the consumer price index.

Cost-benefit analysis

The Canadian market

Canada is the ninth-largest market for drugs and the eighth-largest market for medical devices in the world, representing just over 2.4% of a global market worth approximately US$1 trillion in 2017. In 2015, the Canadian market was estimated to be worth US$24.3 billion ($6.2 billion in medical devices, $3 billion in over the counter medicines, $10.8 billion in prescription patented medicines, and $4.3 billion in generic prescription medicines).

The vast majority of drugs and medical devices sold in Canada are imported from other countries. For instance, Canadian-manufactured generic pharmaceuticals make up just 20.4% of the Canadian market, while Canadian manufactured brand name and innovator pharmaceuticals make up only 8.8% of the Canadian market. Similarly, the Canadian-manufactured medical devices make up just 20% of the Canadian market.

A report published by the Patented Medicines Price Review Board (PMPRB) indicates that Canada is generally the fifth market (following the United States, Sweden, Germany and the United Kingdom) in which new active substances (NASs) are launched.

The fee model

The Government of Canada provides services and regulatory activities that benefit a specific group above the benefit that the general taxpayer receives. One of the key principles behind cost recovery is that, in such cases, the group receiving the additional benefit is expected to pay at least a portion of the costs of these services and activities in the form of fees.

Costs

Price elasticity and passing costs to consumers

The impact of the increase in fees on the price paid by both public and private payers is directly tied to

price elasticity. For NASs, the prices of which are set by the PMPRB, it is likely that the regulatory costs will be absorbed by the industry. In the case of generics and biosimilar drugs, regulatory costs are more likely to be passed on to consumers depending on the level of competition in the product category.

However, in both cases, there are externalities that need to be accounted for. For patented medicines, regulatory changes to the PMPRB framework are designed to protect Canadians from excessive prices for patented medicines. Meanwhile, in the case of generics, a new five-year agreement announced by the Pan-Canadian Pharmaceutical Alliance and the Canadian Generic Pharmaceutical Association came into effect on April 1, 2018. The Agreement should facilitate price reductions of nearly 70 of the most commonly prescribed drugs by between 25% and 40%. Price caps such as the two examples above may limit industry's ability to pass increased regulatory costs onto payers leaving industry more likely to absorb these costs.

For medical devices, there is no one body that sets prices and it is likely that regulatory costs would be passed on to payers when the likelihood of product substitution is low, but absorbed by industry when the likelihood of product substitution is high.

Decision not to market in Canada

It is conceivable that there may be situations in which the fees could undermine the commercial viability of a product. In such instances, industry may decide not to market the product in Canada. As a result, Canadians may be denied access to that product.

The likelihood of this scenario is lessened by the limited price sensitivity of some medical devices and human drugs, which have more unique characteristics than most traditional consumer goods.

Another reason the increase in fees may not influence the decision to market in Canada is that the Canadian market is expected to remain lucrative given the rising demand in the near to mid future due to aging populations. Consequently, despite an increase in fees, the margins on new products should continue to be competitive vis-à-vis global markets.

Indeed, despite Canada's current lower fees and competitive performance standards, industry rarely launches products in Canada first. As noted, industry comes to Canada fifth, on average, which is most likely related to the way pricing is currently set by the PMPRB, and due to corporate limitations to launch products in multiple jurisdictions simultaneously.

Health Canada maintains various mechanisms to ensure that products may still be brought into the country if there is a need. These mechanisms are the Special Access Programme and certain provisions in the *Food and Drug Regulations* that permit the importation of drugs when necessary to meet an urgent public health need.

Overall, it is expected that in the vast majority of cases, the increase in fees would not affect the availability of products on the Canadian market.

Benefits

Reduced burn rates and opportunity costs

Research and development costs for new patented medicines are high. Citing a Tufts University study and subsequent updates, Innovation, Science and Economic Development Canada indicated that research and development (R&D) costs per drug averaged US$1.4 billion over a 12–13 year period.

Full costing (amortization of research failures and opportunity cost of capital) raised the average costs to an estimated US$2.6 billion. However, these figures for the cost and length of development are controversial and have often been disputed. In fact, their actual value may be as much as 80% lower.

According to the fourth in a series of comprehensive compound-based analyses of the costs of new drug development, the estimated total out-of-pocket and capitalized R&D costs per new drug were $1.4 billion and $2.6 billion in 2013 U.S. dollars, respectively. Examining R&D costs over the entire product and development life cycle increased the out-of-pocket cost per approved drug to $1.9 billion, and the capitalized cost, to $2.9 billion. When compared to the results of the previous study in the series, total capitalized costs were shown to have increased at an annual rate of 8.5% above general price inflation.

The costs of developing generics are less contentious. The Canadian Generic Pharmaceutical Association suggests that bringing a generic product to the Canadian market costs somewhere in the range of $3.5 million and takes three to six years. This includes the costs for bio-equivalence studies, development and regulatory approval.

This new modernized cost recovery regime helps support Health Canada's ability to produce timelier regulatory decisions. Timelier regulatory decisions are expected to benefit industry in terms of reduced burn rate (the rate at which a company spends money in excess of income) and lower opportunity cost (the

benefit that a company could have received had it pursued another option). For example, the sooner a therapeutic product manufacturer receives a negative regulatory decision, the sooner the manufacturer can decide to terminate or change its approach to product development, thereby allowing it to cut its losses and redeploy its resources earlier. Alternatively, if the regulatory decision proves to be favourable, the manufacturer can bring that product to market and generate revenues earlier.

As an example, the PMPRB reports that of 210 NASs brought to Canada between 2009 and 2014, sales at the individual drug level of the top 30 NASs exceeded $250 million per year, while the sales at the low end represented drug sales worth $25 million. More timely regulatory decisions would allow the market authorization holders of these products to access the market sooner and recoup their development and regulatory costs earlier.

Prior to the ministerial order, Health Canada was only required to meet its approval timelines on a cumulative average basis. That is to say, the average of all of Health Canada's approvals in a given category was required to meet the performance standard. If Health Canada failed to meet this requirement, fees were reduced for the subsequent year. Under the ministerial order, Health Canada is required to meet its standards in each case or apply a fee remission to the affected company.

Consultation

In April 2017, Health Canada communicated its intent to update fees and began its engagement process with stakeholders. Industry associations from various sectors were engaged. These sectors included medical devices, disinfectants, generic drugs, biosimilar drugs, innovator/biological drugs, over-the-counter (non-prescription) drugs, radiopharmaceutical drugs and veterinary drugs. A number of individual companies were also engaged.

Health Canada also undertook a number of stakeholder engagement events. These events included the following:

- industry bilateral meetings;
- cost recovery renewal initiative stakeholder WebEx;
- information session;
- information clarification session;
- sector-specific sessions — fee proposal; and
- sector session calls — revised fee proposal.

A report including stakeholder feedback received throughout the consultations and the responses from Health Canada will be published on the Health Canada website.

Fee proposal — October 11, 2017

On October 21, 2017, Health Canada published a notice of intent to consult in the *Canada Gazette*, Part I, on Health Canada's *Fee Proposal for Drugs and Medical Devices* and informed all licence and drug identification holders of the consultations. In addition, Health Canada posted its fee proposal on the Department's website on October 11, 2017. At the time, a costing companion document was also made available by the Department.

Industry associations from the following sectors were engaged: medical devices, disinfectants, generic drugs, biosimilar drugs, innovator/biological drugs, over-the-counter (non-prescription) drugs, radiopharmaceutical drugs and veterinary drugs. Stakeholders actively participated in the consultation process.

The main concerns raised during the consultation process and summarized below included the magnitude of the fee increases, the lack of staggered implementation and the proposed approach to small business:

- *Fee setting and timing of implementation*: Stakeholders generally supported Health Canada's need to update fees and recognized that current fees were out of date. However, many were concerned with how much the fees were increasing and the potential negative impacts on the financial growth of companies, especially with respect to the fee for right to sell.
- *Costing*: Several stakeholders expressed concern regarding Health Canada's costing methodology and perceived lack of transparency. Stakeholders established that they wanted more clarity on how costs were calculated.
- *Small business mitigation measures*: Stakeholders welcomed Health Canada's position to consider the needs of small business. However, some stakeholders were concerned with the impact of eliminating the current mitigation measures under the *Fees in Respect of Drugs and Medical Devices Regulations*.

Revised fee proposal — May 24, 2018

The input received by stakeholders during this consultation process was instrumental to the development of a revised fee proposal. The revised fee proposal included the following measures to address stakeholder

concerns:

- phased-in implementation limiting the amount by which a fee can increase in any given year;
- reduced fee-setting ratios; and
- expansion of small business mitigation measures to all fee lines, added mitigation measures for publicly funded health care institutions, and pro-ration of the DEL fee for new applicants.

Spring 2018 feedback process

The revised fee proposal was published on Health Canada's website on May 24, 2018. Health Canada held a WebEx for stakeholders on June 1, 2018. In addition, stakeholders were also invited to submit feedback on the revised proposal from May 24, 2018, to June 14, 2018.

In the May 2018 revised proposal, the same DEL fees were applied to both human and veterinary drug establishments. However, some of these fee increases were perceived as too large by veterinary stakeholders since veterinary drugs were not part of the previous cost recovery fee update in 2011. This view was compounded by concerns regarding additional regulatory requirements on industry to conform to the new *Regulations Amending the Food and Drug Regulations (Veterinary Drugs — Antimicrobial Resistance)*.

In response to industry concerns, targeted reductions and an extension of the phase-in period from four to seven years have been granted for DEL fees through the ministerial order for establishments that only deal with veterinary products.

"One-for-One" Rule

This ministerial order is not expected to introduce a new administrative burden on business.

Small business lens

Health Canada's approach to fee mitigation is focused on facilitating Canadians' access to products in order to help them maintain and improve their health. Companies that meet the definition of a small business under the ministerial order qualify for significant fee remissions and will pay between 25% and 50% less than other companies. All "first-time" pre-market evaluation submissions or applications by small businesses will qualify for a full remission of their evaluation fees.

Additional mitigation measures being proposed include an exemption from the application of the ministerial order for all publicly funded health care institutions, and a remission of fees for submissions concerning drugs that may be imported for an urgent public health need, as well as for quarterly pro-rated DEL fees for new applicants.

Implementation, enforcement and service standards

A communication strategy will include notices to stakeholders regarding the revised fees, as well as updated guidance documents for stakeholders and posting on Health Canada's website. Revised fees will be posted in the fall of each year, reflecting adjusted fees based on the consumer price index.

With respect to enforcement, if a person fails to pay a fee, then the fee payable will become a debt owing to the Crown, which would be collected in accordance with standard practices. The Minister also has the authority to withhold or withdraw a service or a right or privilege from any person who fails to pay the fixed fee. Regarding small business remissions, the Minister will have the ability to request additional information to assess whether the company qualified as a small business at the time of filing their submission or other required material. Where the additional information is not provided within 60 days, or the Minister determines that the person did not qualify as a small business at the time of their filing, the applicable fee has to be paid in full, with interest from the date of the initial filing.

With respect to performance standards, Health Canada has consulted both fee-paying and non–fee-paying stakeholders. For each fee, Health Canada has identified a performance standard that reflects the level of service that can be expected.

Performance standards will not only be the expected level of service, but will become a service commitment, with remission consequences applied if standards are missed. Public performance reporting on performance standards, remissions, costs and revenues will continue through the appropriate mechanisms as directed by the Treasury Board Secretariat.

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Canada Gazette, Part 2, Volume 153, Number 11: Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act

Canada Gazette, Part II, Volume 153, Number 11

Registration

SOR/2019-134 May 10, 2019

FINANCIAL ADMINISTRATION ACT

P.C. 2019-483 May 9, 2019

Her Excellency the Governor General in Council, on the recommendation of the Treasury Board and the Minister of Health, pursuant to subsection 19(1) and section 19.1[footnote a] of the *Financial Administration Act*, and, considering that it is no longer in the public interest to remit certain debts but that it is otherwise in the public interest to remit other debts, subsection 23(2.1) of that Act, makes the annexed *Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act*.

Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act

Fees in Respect of Drugs and Medical Devices Regulations

1 The title of the *Fees in Respect of Drugs and Medical Devices Regulations* is replaced by the following:

Fees in Respect of Dealer's Licences Regulations

2 Section 1 of the Regulations and the headings before it are repealed.

3 The heading before section 2 of the Regulations is repealed.

4 Subsection 2(1) of the Regulations is replaced by the following:

Purpose — fees

2 (1) The purpose of these Regulations is to prescribe the fees for the examination of an application for, or the renewal of, a dealer's licence under Part G of the *Food and Drug Regulations* or under the *Narcotic Control Regulations*.

5 Section 3 of the Regulations and the heading before it are repealed.

6 The heading before section 4 of the Regulations is repealed.

7 The headings before section 5 and sections 5 to 28 of the Regulations are repealed.

8 The headings before section 29 of the Regulations are repealed.

9 (1) The portion of subsection 29(1) of the Regulations before the first definition is replaced by the following:

Definitions

29 (1) The following definitions apply in sections 30, 31 and 33.

(2) Subsection 29(2) of the Regulations is replaced by the following:

Words and expressions

(2) Unless the context otherwise requires, all other words and expressions used in sections 30, 31 and 33 have the meaning assigned to them by the *Controlled Drugs and Substances Act*, Part G of the *Food and Drug Regulations* or the *Narcotic Control Regulations*.

10 The heading before section 30 of the Regulations is repealed.

11 (1) The portion of section 30 of the Regulations before paragraph (a) is replaced by the following:

Non-application — applicants

30 (1) These Regulations do not apply to

(2) Section 30 of the Regulations is amended by adding the following after subsection (1):

Non-application — drug for veterinary use only

(2) These Regulations do not apply to a drug that is for veterinary use only.

12 The heading before section 31 of the Regulations is repealed.

13 Subsection 31(2) of the Regulations is replaced by the following:

Remission

(2) Subject to subsection 33(2), if the fee is greater than an amount equal to 1% of the applicant's actual gross revenue from activities conducted under a dealer's licence during the previous calendar year, remission is granted of the difference between those amounts if the applicant provides with their application a statement signed by the individual responsible for the applicant's financial affairs that sets out the actual gross revenue.

14 Section 32 of the Regulations is repealed.

15 The headings before section 34 and sections 34 to 53 of the Regulations are repealed.

16 Schedules 1 to 7 to the Regulations are repealed.

Repeals

17 The following Regulations are repealed:

- **a) the *Authority to Sell Veterinary Drugs Fees Regulations*;**
- **b) the *Veterinary Drug Evaluation Fees Regulations*; and**
- **c) the *Establishment Licensing Fees (Veterinary Drugs) Regulations*.**

Transitional Provisions

18 The *Veterinary Drug Evaluation Fees Regulations*, as they read immediately before the day on which the *Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act* come into force, continue to apply in respect of an application submitted under subsection 16(2) of the *Veterinary Drug Evaluation Fees Regulations* before that day.

19 The *Establishment Licensing Fees (Veterinary Drugs) Regulations*, as they read immediately before the day on which the *Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act* come into force, continue to apply in respect of

- **(a) a fee whose payment is deferred under subsection 12(2) of the *Establishment Licensing Fees (Veterinary Drugs) Regulations* to a day that is on or after that day; and**
- **(b) a remission referred to in section 11 of the *Establishment Licensing Fees (Veterinary Drugs) Regulations*.**

20 The *Fees in Respect of Drugs and Medical Devices Regulations*, as they read immediately before the day on which the *Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act* come into force, continue to apply in respect of

- **(a) a fee whose payment is deferred under subsection 9(1), section 10 or subsection 17(4), 35(4), 43(1), 48(3) or 51(4) of the *Fees in Respect of Drugs and Medical Devices Regulations* to a day that is on or after that day; and**
- **(b) a remission referred to in section 11, subsection 17(2), section 44 or subsection 51(2) of the *Fees in Respect of Drugs and Medical Devices Regulations*.**

Coming into Force

21 These Regulations come into force on April 1, 2020, but if they are registered after that day, they come into force on the day on which they are registered.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations*.)

Issues

Recent amendments to the *Food and Drugs Act* (FDA) were made through the *Budget Implementation Act, 2017, No. 1* (BIA), and gave the Minister of Health (the Minister) the authority to fix, by ministerial order, fees for activities and products that are regulated under the FDA (e.g. human and veterinary drugs as well as medical devices). These amendments allow Health Canada (the Department) to modernize its current fee regime for recovering costs for regulatory activities related to these products. Currently, these fees are set out in four sets of regulations that have been made under the *Financial Administration Act* (FAA):

- (1) *Fees in Respect of Drugs and Medical Devices Regulations*;
- (2) *Authority to Sell Veterinary Drugs Fees Regulations*;
- (3) *Veterinary Drug Evaluation Fees Regulations*; and
- (4) *Establishment Licensing Fees (Veterinary Drugs) Regulations*.

In order to implement this new fee regime, the *Fees in Respect of Drugs and Medical Devices Regulations* must be repealed in part and amended. The following regulations must be repealed in their entirety: the *Authority to Sell Veterinary Drugs Fees Regulations*, the *Veterinary Drug Evaluation Fees Regulations* and the *Establishment Licensing Fees (Veterinary Drugs) Regulations*.

The new fee regime will apply as of April 1, 2020. However, transitional provisions are needed to allow for the continuation of existing fee deferrals and remissions past the repeal of the deferrals and the coming into force of the ministerial order.

Background

Health Canada regulates the safety, efficacy and quality of health products. Since 1995, the Department has been charging fees in accordance with the above-mentioned FAA regulations for certain services and activities related to the regulation of health products (including pharmaceutical and biologic drugs, medical devices and veterinary drugs) under the FDA. These fees apply to such activities as pre-market regulatory reviews, the ongoing surveillance of products once they are on the market, the examination of drug establishment licence applications and the inspection of drug establishments conducting regulated activities.

Health Canada last updated its fees relating to human drugs and medical devices in 2011, based on 2007 costs. Fees for veterinary drugs were implemented in stages between 1995 and 1998, and have not been updated since that time. Prior to 2017, fees relating to therapeutic products could only be changed through a regulation made by the Governor in Council that met requirements found under the former *User Fees Act*. This process took several years. As a result, Health Canada's fees for activities/services related to drugs (human/veterinary) and medical devices were not able to keep up to date with the evolving costs associated with these activities/services. As a consequence, Health Canada's fees for drugs and medical devices no longer reflect current costs to the Department, nor are they well aligned with fees charged by regulatory partners. This means that the portion of the costs covered by fee payers has decreased over time, with the remaining costs being paid by Canadian taxpayers.

In 2017, amendments made to the FDA through the BIA provided the Minister with the authority to fix fees through a ministerial order. These amendments require the Minister to consult stakeholders prior to fixing fees, they prohibit fees from exceeding the cost of providing a service, and they exempt these fees from the requirements of the *Service Fees Act* (formerly the *User Fees Act*).

By being able to set fees through a ministerial order under the FDA, the Minister now has the flexibility to set and adjust fees in a timely way so that they better reflect actual costs and allow Health Canada to more effectively deliver its regulatory programs.

While the Department can set fees under the FDA in a timely manner, all fee updates and revisions will continue to respect transparency and accountability principles, including provisions for financial consequences for not meeting performance standards and annual reporting.

Objectives

Amendments to the *Fees in Respect of Drugs and Medical Devices Regulations* and the repeal of the *Authority to Sell Veterinary Drugs Fees Regulations*, the *Veterinary Drug Evaluation Fees Regulations* and the *Establishment Licensing Fees (Veterinary Drugs) Regulations*, all of which fall under the FAA,

will provide clarity to stakeholders on which set of fees are in force and prevent duplicative fees. Establishing transitional provisions will also allow for the continuation of existing fee deferrals and remissions past the implementation of the ministerial order. Ultimately, stakeholders will be subject to the fees fixed by a new ministerial order under the FDA.

Description

The *Fees in Respect of Drugs and Medical Devices Regulations* will be repealed in part and amended. The provisions that remain will be those that relate to the fees for dealer's licences that are issued under the *Narcotic Control Regulations* and Part G of the *Food and Drug Regulations*, both of which fall under the purview of the *Controlled Drugs and Substances Act* (CDSA). As these FAA fees relate to activities governed under the CDSA, they cannot be prescribed through ministerial orders under the FDA. Also, the name of the *Fees in Respect of Drugs and Medical Devices Regulations* will be changed to "*Fees in Respect of Dealer's Licences Regulations*," which more accurately reflects the fact that the remaining provisions under the FAA only cover fees with regard to dealer's licences governed under the CDSA.

The *Authority to Sell Veterinary Drugs Fees Regulations*, the *Veterinary Drug Evaluation Fees Regulations* and the *Establishment Licensing Fees (Veterinary Drugs) Regulations* will be repealed in their entirety.

Through the establishment of transitional provisions, the application of regulations that deal with fee deferrals and remissions will continue. As an example, if a company qualifies for a fee deferral in February 2020, the deferral will continue to apply past the repeal of the deferral and the coming into force of the ministerial order. These transitional provisions will allow for the deferral and any requirements associated with it to continue to apply once the ministerial order comes into force.

The partial repeal and amendments to the *Fees in Respect of Drugs and Medical Devices Regulations*, the repeal of the *Authority to Sell Veterinary Drugs Fees Regulations*, the V*eterinary Drug Evaluation Fees Regulations*, and the *Establishment Licensing Fees (Veterinary Drugs) Regulations*, and the respective transitional provisions will come into force on April 1, 2020, the same day that the ministerial order comes into force.

"One-for-One" Rule

The "One-for-One" Rule applies since three regulations are repealed; as a result, three titles are counted "out" under the Rule.

Small business lens

The small business lens does not apply, as these regulatory amendments do not impose any costs on businesses.

Consultation

Between October 2017 and June 2018, the Department conducted extensive consultations with affected stakeholders on the new cost recovery proposal to be set by ministerial order. It proposed changes to the fees for human/veterinary drugs and medical devices, fee mitigation strategies, financial consequences provisions for when performance does not meet set performance standards, and annual fee adjustments tied to the consumer price index. Consultations ranged from WebEx presentations, sector-specific face-to-face sessions, and teleconferences. In October 2017, the Department published an initial consultation document to seek stakeholder feedback. In May 2018, a revised proposal responding to reactions from stakeholders was published to seek additional feedback. All stakeholder comments resulting from these extensive consultations have been considered. The Regulatory Impact Analysis Statement accompanying the ministerial order replacing the repealed regulations explains this further.

Rationale

The *Fees in Respect of Drugs and Medical Devices Regulations* must be repealed in part and amended and the *Authority to Sell Veterinary Drugs Fees Regulations*, the *Veterinary Drug Evaluation Fees Regulations*, and the *Establishment Licensing Fees (Veterinary Drugs) Regulations* must be repealed in order to avoid the duplication of fees, and to provide clarity to stakeholders on which set of fees are in force, once the Department's new fees under the ministerial order are made. Transitional provisions are also necessary to allow for the continuation of existing fee deferrals and remissions at or after the time of the repeal.

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