

July 4, 2011

Notice

Our file number: 11-112473-423

Guidance Document - Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices

Please find attached the new document *Guidance Document - Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices*. This guidance document replaces the August 23, 2005 version of the document *Guidance for Industry - Medical Device Licence Renewal*.

The *Guidance Document - Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices* provides manufacturers and regulatory correspondents guidance on the steps involved in renewing a medical device licence to fulfil their obligation under section 43 of the *Medical Devices Regulations*. In addition, the document explains the fees to be paid by manufacturers at the time of renewal for the right to sell a device. These fees are in accordance with Division 3 Fee for the Right to Sell Licensed Class II, III or IV Medical Devices contained in *Fees in Respect of Drugs and Medical Devices Regulations*.

For more information on Medical Device Licence Renewal, please contact:

Licence Renewal
Medical Devices Bureau
Health Products and Food Branch
150 Tunney's Pasture Driveway
Room 1605, Main Building
Address Locator 0301H1
Ottawa Ontario
K1A 0K9
Canada

Telephone: 613-946-6555
Fax: 613-946-6563
Email: Licence_Renewal@hc-sc.gc.ca



GUIDANCE DOCUMENT

Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices

Published by authority of the
Minister of Health

Date Adopted	2004/09/15
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Health Products and Food Branch

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by:</p> <ul style="list-style-type: none"> • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre :

Ligne directrice - Renouvellement de l'homologation d'un matériel médical et frais à payer pour le droit de vendre un instrument médical homologué

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

Document Change Log	
Version Guidance Document - Medical Device Licence Renewal and Fees for the Right to Sell Licensed Medical Devices	Replaces Guidance for Industry - Medical Device Licence Renewal
Date 2011/ 07/01	Date 2005/08/17

Change
The guidance document for medical device renewal was rewritten to incorporate guidance on the cost recovery regulations entitled the <i>Fees in Respect of Drugs and Medical Devices Regulations</i> . Significant changes to this document include changes in the fee structure and in the fee deferral process.

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1.0 INTRODUCTION

This guidance document provides medical device manufacturers and their regulatory correspondents with the steps involved in renewing a medical device licence. The renewal process has two purposes: the first is to confirm whether the medical device will continue to be sold in Canada and the medical device licence will remain active; the second is to collect information that must be assessed prior to invoicing for the right to sell fee.

This guidance document also provides guidance on the *Fees in Respect of Drugs and Medical Devices Regulations* (Fee Regulations) with a focus on how the Fees for the Right to Sell Licensed Class II, III or IV Medical Devices, contained in Part 3, Division 3 of these regulations, will be administered.

1.1 Policy Objective

To ensure that the information in Health Canada's records pertaining to medical devices that are on the Canadian market is current and accurate.

To ensure that the cost recovery system to defray the cost to government of applying the principles of risk assessment and risk management in the regulation of medical devices reflects the current costs associated with the marketing of medical devices.

1.2 Policy Statements

Manufacturers of medical devices that are licensed for sale, in Canada, are required to inform Health Canada each year before November 1 that the information submitted with their licence application and any subsequent amendments has not changed. This is referred to as the licence renewal process.

Manufacturers of licensed Class II, III and IV medical devices are charged an annual fee, payable at the time of licence renewal, for the right to sell their devices in Canada.

If the annual gross revenue (AGR) in respect of the sale of a medical device, along with the sale of any other medical devices in the same medical device family, in Canada, during the previous calendar year is less than \$20,000 then the fee for the right to sell is \$50 in accordance with Section 48. (1) (a) of the Fee Regulations. In all other cases the fee is \$330.

Manufacturers that have not completed their first calendar year of selling their medical device in Canada will have their fee deferred for the right to sell that device to the end of that year.

The right to sell fee is to be increased annually by 2%, rounded up to the nearest dollar, beginning on April 1, 2012.

1.3 Scope and Application

This guidance document applies to Class II, III and IV medical devices for which medical device licences have been issued by Health Canada. It covers the application of Section 43 of the *Medical Devices Regulations* (MDR) and Division 3 of the Fee Regulations.

1.4 Background

The promulgation of the MDR in 1998 set forth legislation prohibiting the sale in Canada of Class II, III, and IV devices without a medical device licence.

Medical device licences are granted bearing an Issued Date. There is no expiry date. However, Section 43 of the MDR requires every manufacturer of a licensed medical device or their authorized regulatory correspondent to confirm annually, before November 1, that the information held by Health Canada is accurate, or that amendments to correct the information will be made. Failure to do so may result in cancellation of the licence.

In the late 1990s, Health Canada was given the authority under the *Financial Administration Act* to charge industry user fees in order to recover some of the costs related to service delivery for medical devices. However, the cost of service delivery has increased substantially since that time due to increasing volume and complexity of applications, along with costs of inflation and other costs of doing business.

The Fees for the Right to Sell Licensed Class II, III or IV Medical Devices contained in Part III of the Fee Regulations aim to provide sufficient funding for Health Canada to meet service standards; to keep current with the assessment of signals and safety trends; and to produce risk communications concerning all regulated marketed health products. They also address costs associated with inflation.

1.5 Definitions

Annual Gross Revenue - The amount earned by the manufacturer in respect of the sale of a licensed medical device, along with the sale of any other medical devices in the same medical device family, in Canada, during the previous calendar year.

Calendar Year - A period of twelve consecutive months commencing on January 1.

First Completed Calendar Year - The completion of a period of twelve consecutive months commencing on January 1 following the date on which the licensed medical device was marketed in Canada.

Licence Renewal - refers to the obligation to annually inform the Minister of Health as described in Section 43 (1) (a) and (b) of the MDR.

Manufacturer (as defined in the MDR) - is a person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Regulatory Correspondent - a person authorized by the manufacturer to act on their behalf.

Medical Device Licence - refers to medical device licences issued by the Medical Devices Bureau on behalf of the Minister for Class II, III and IV medical devices sold in Canada.

1.6 Acronyms

AGR	Annual Gross Revenue
MDB	Medical Devices Bureau
MDR	<i>Medical Devices Regulations</i>
TPD	Therapeutic Products Directorate

2.0 ANNUAL LICENCE RENEWAL

This section provides detailed information on how to renew a medical device licence.

2.1 General Contact Information for Renewal and Right to Sell Fees for Licensed Medical Devices

For questions regarding licence renewal, contact the Medical Devices Bureau by phone at 613-946-6555 or 613-946-6553; by fax at 613-946-6563; or by email at License_Renewal@hc-sc.gc.ca.

For questions related to the interpretation of the *Fees for the Right to Sell Licensed Class II, III or IV Medical Devices* as it applies to your application, including invoice disputes, contact the Medical Devices Bureau, Device Licensing Services Division by phone 613-957-7285 or by email at mdb_enquiries@hc-sc.gc.ca.

For questions regarding your invoice payment or your account balance, contact Accounts Receivable by phone at 613-957-1052 or 1-800-815-0506; by fax at 613-957-3495; or by email at AR-CR@hc-sc.gc.ca. Please have your customer account or invoice number available.

2.2 Licence Renewal Procedure

Early in August of each year, Health Canada sends each manufacturer who is marketing licensed Class II, III or IV medical devices in Canada an annual licence renewal package. By doing so Health Canada intends to help the manufacturer to fulfil their regulatory obligation under Section 43 of the MDR. If the manufacturer has provided Health Canada with the name and address of their regulatory correspondent the renewal package will be sent to that person instead of to the manufacturer. If the renewal package has not been received by September 1, the manufacturer or their regulatory correspondent should request the package using the renewal contact information listed above.

Note: It is important that the manufacturer notify Health Canada if there is a change regarding the regulatory correspondent or contact information previously submitted. Failure to do so may result in the cancellation of a licence.

2.2.1 Annual Renewal Package

The renewal package contains the following where appropriate:

- The Annual Medical Device Licence Renewal Form with instructions for its completion and return.
- A Reduced Fee Request and Certification Form to be completed for the devices that have completed a full calendar year on the market.
- A separate list of devices whose fees were deferred to the end of their first calendar year on the market which they are about to complete. Attached to this list is a Reduced Fee Request Form to be completed for devices on this list if they are eligible for the reduced right to sell fee (see 3.5 Deferred Payments). The form must be submitted to the Medical Devices Bureau (MDB) by January 20, allowing for review of the request and an accurate invoice for the right to sell fee to be sent in February.
- May contain additional information concerning new regulatory issues.

2.2.2 Annual Medical Device Licence Renewal Form

A renewal form is generated for each manufacturer. A sample renewal form (for illustration purposes only) may be found at the end of this document as Appendix 1.

The Renewal Form contains the following information:

- the regulatory correspondence address of the manufacturer;
- the name of the manufacturer's contact person and their contact information;
- the attestation section;

- section 43 of the MDR;
- the name of the manufacturer;
- a listing of all the manufacturer's licensed devices, their licence number and class that have been on the market for more than a calendar year;
- a listing of the devices whose fees are deferred to the end of their first calendar year but no invoice is needed as they have not yet commenced their first calendar year. Calendar year is defined as January 1 to December 31. See 3.5 Deferred Payments below.
- a listing of devices whose fees were deferred to the end of their first calendar year on the market which they are about to complete and for which an invoice for the right to sell fee will be sent in February.

Note: Licences issued after July 27 are not included on this form. All new licences issued between July 27 and November 1 will be automatically renewed. This action will reduce the administrative burden to manufacturers and to MDB. Manufacturers are still required to pay a renewal fee for new licences issued between July 27 and November 1 although payment will be deferred (see 3.5 Deferred Payments below). Manufacturers that are issued new licences between July 27 and November 1 will be provided with a renewal advisory when their medical device licence is mailed to them.

Instructions for Completing the Renewal Form:

- Correct any changes to the name of the contact person or their contact information in the space provided to the right of the contact information.
- A senior official of the “manufacturer” or their designated regulatory correspondent must sign the attestation.
- Indicate medical device licences that should be discontinued by placing an [X] beside the medical device licence number in the discontinue column. This means that the manufacturer has stopped marketing the device or family of devices in Canada.
- If all the products for which medical device licences that are listed have been withdrawn from the Canadian market, place an [X] in the appropriate column indicating that all the licences are to be discontinued.
- If all the products for which medical device licences that are listed are to remain on the Canadian market, place an [X] in the appropriate column.

As noted above, if the relationship between a regulatory correspondent and a manufacturer is no longer in effect, the manufacturer must notify MDB of the change as well as who is attending to their regulatory matters, that is (i.e.) either the manufacturer or a new regulatory correspondent. Failure to do so may result in cancellation of the licence.

Changes not accepted on the Renewal Form

Changes to information other than changes to the contact information and notification of discontinuance must be made by submitting the appropriate amendment forms listed below and available on the Health Canada website:

- *Medical Devices Licence Amendment Fax-Back Form - Guidance for Non-Significant Additions/Deletions (non-significant changes to catalogue numbers);*
- *Medical Devices Licence Amendment Fax-Back Form - Guidance for Changes to Manufacturer's Name and/or Address of Existing Device Licences;*
- *Licence Amendment Fax-Back Form - Guidance for Changes to the Name of a Device for Existing Device Licences;*
- *Class II Medical Device Licence Amendment Application Form;*
- *Class III Medical Device Licence Amendment Application Form;*
- *Class IV Medical Device Licence Amendment Application Form.*

2.2.3 Return of the Renewal Form and the Reduced Fee Request Form

The completed renewal form must be returned to the Device Licensing Services Division of MDB before November 1 of the year it is received (see address below). If applicable, completed Reduced Fee Request and Certification Forms must also be returned at the same time except where the fee is being deferred (see 3.3 Reduced Fee Request and Certification Form and 3.5 Deferred Payments below).

Note: No fee payment should accompany the return of the forms (see 2.2.4 Processing the Renewal Form and Invoicing below).

Where to Send Forms

Licence Renewal forms should be sent to the following address:

Licence Renewal
Medical Devices Bureau
Health Products and Food Branch
150 Tunney's Pasture Driveway
Room 1605, Main Building
Address Locator 0301H1
Ottawa Ontario
K1A 0K9
Canada

2.2.4 Processing the Renewal Form and Invoicing

Renewal applications and any reduced fee requests are processed on receipt. A description of the medical device licences renewed and the fees assessed accompanies the invoice. The invoices are mailed in February for payment within 30 days. The invoice documentation confirms renewal of the medical device licence(s). No new medical device licences are issued as a result of the renewal process.

2.2.5 Failure to Renew

Failure to comply with section 43 of the MDR may result in cancellation of existing medical device licences. The invoicing process will bill only valid renewed medical device licences for which fee payment has not been deferred (see 3.5 Deferred Payments). Medical device licences not renewed have either been discontinued by the manufacturer, or have been cancelled by MDB for failure to renew by the November 1 deadline.

If a medical device licence has been cancelled, the product is no longer permitted to be offered for sale in Canada. In order to bring the medical device back into compliance, the manufacturer or regulatory correspondent is required to submit a new medical device licence application, as well as pay all applicable fees.

3.0 FEES FOR THE RIGHT TO SELL LICENSED MEDICAL DEVICES

Health Canada carries out post-market monitoring and assessment of medical devices. The fees for the right to sell a licensed medical device are used to pay for a portion of these activities. The fees are charged annually for the twelve month period beginning on November 1 of each year.

3.1 Fee Schedule

Part 3 (Division 3) of the Fee Regulations sets out the following fee schedule, based on AGR:

Annual Gross Revenue from the sales of the medical device and any other devices in the same medical device family during the previous calendar year	Fee to be paid for the right to sell the medical device
Less than \$20,000	\$50
\$20,000 or more	\$330

As shown above, the standard fee set out in the Fee Regulations is \$330; however, manufacturers may be eligible to apply for the reduced fee of \$50 (see 3.3 Reduced Fee Request and Certification Form).

Adjustment of Fees

The right to sell fee is to be increased annually by 2%, rounded up to the nearest dollar, beginning April 1, 2012; i.e., in 2012, the standard fee will be \$337 and the reduced fee will be \$51. An annual adjustment factor is necessary to ensure that service standards continue to be met. Each year, a Notice of Intent will be published in *Canada Gazette, Part I* setting out the revised fees. Additionally, Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of those reviews, if necessary.

3.2 Timing of Payment and Invoicing

The fee is payable at the time the manufacturer provides Health Canada with the information referred to in subsection 43 (1) of the MDR. However, manufacturers must wait for the invoice, sent in February, before submitting payment.

3.3 Reduced Fee Request and Certification Form

In order to qualify for the reduced fee, the manufacturer must submit a completed Reduced Fee Request and Certification Form with their renewal. This form must be signed by the individual responsible for the manufacturer's financial affairs certifying that the AGR from the sales of the medical device for which a licence has been issued, along with any other devices in the same medical device family, is less than \$20,000. A sample copy of this form is attached in Appendix 2. Health Canada will review the documentation and respond appropriately.

3.4 Audited Sales Records

The Fee Regulations contain a provision to permit Health Canada to verify the AGR. If Health Canada has information indicating that the statement provided by the manufacturer to support their AGR is inaccurate, then the manufacturer may be required to produce sales records (due within 60 days of the request) that have been audited by a qualified independent auditor. The sales records will then be used to determine the fee payable or the amount of the remission by Health Canada.

If the manufacturer fails to provide the audited sales records to Health Canada within 60 days, the difference between the reduced fee and the standard fee is immediately payable.

If the audited sales records establish that the amount paid was incorrect, the difference between the reduced fee and the standard fee is immediately payable.

3.5 Deferred Payments

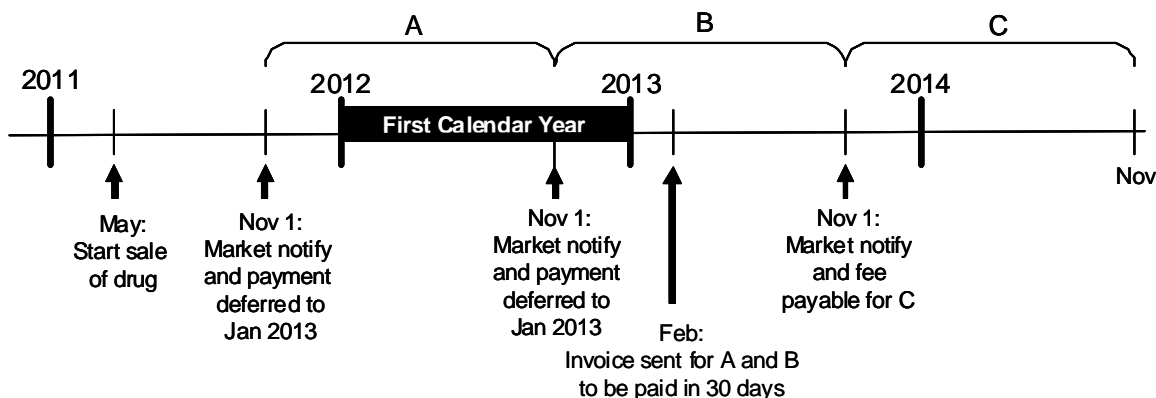
Section 48. (3) of the Fee Regulations states that if the manufacturer has not completed its first calendar year of selling a medical device, the payment of the fee is deferred to the end of the first complete calendar year that the medical device is on the market (i.e., is payable on January 1 following completion of that year). This deferral provides an opportunity for manufacturers to accumulate AGR data from the sale of the new product in its first calendar year to determine if they are eligible for the reduced fee (see section 3.3).

The total fee payable on January 1 includes the fee for each period of November 1 to October 31 that has commenced. **Note that although the fee is payable January 1, Health Canada does not issue the invoice until February. The fee is due within 30 days following issuance of the invoice.**

Figure 1 shows an example of when payments would be due for a product commencing sale in May 2011. The fee payment for period A is deferred to the end of the first calendar year and is payable January 1, 2013. The fee payment for period B is also deferred to January 1, 2013. In February of 2013, the manufacturer will be invoiced as follows:

$$\$330 \text{ (period A)} + \$330 \text{ (period B)} + 2\% \times \$330 \text{ (annual increase)} = \$667$$

Figure 1



Deadline for Submission of Reduced Fee Request and Certification for Deferred Fees

As stated above, the reason for the fee deferral is to provide an opportunity for manufacturers to accumulate AGR data from the sale of a new product in its first calendar year to determine if it is eligible for the reduced fee. In Figure 1 the first complete calendar year is 2012. Therefore, eligibility for a reduced fee for periods A and

B would be based on the AGR in 2012 from the sale of the device along with the sale of any other medical devices in the same medical device family.

The manufacturer must be ready to submit their request for a reduced fee in respect of the newly marketed device no later than January **20** of the year following the first completed calendar year that the device was on the market. If January 20 falls on a weekend then the deadline for submission falls to the first Monday following January **20**. If the manufacturer fails to submit the request before the deadline then an invoice for the standard fee will be sent.

The following is an example of a Medical Device Licence Renewal Form. It is included for illustration purposes only, and it is not to be submitted to the Medical Devices Bureau. A genuine renewal form contains data for a particular manufacturer and lists the medical device licences issued to that manufacturer.

Medical Devices Licence Renewal Form		Therapeutic Products Directorate Medical Devices Bureau
RETURN TO BUREAU		
Mailing Address for Regulatory Correspondence		
Regulatory Contact	Please make any corrections in this column	
Name:	Sample only Do not use this form	
Title:		
Phone:		
Extension:		
Fax:		
Email:		
Language:		
Attestation		
I hereby attest that I have knowledge of the information supplied in this application for licence renewal, that the information and documents supplied at the time of application or subsequent amendment with respect to the devices listed in this report are still correct, or the product has been identified as discontinued.		
<hr/> Name of Signing Official (please print)		
<hr/> Company Name		
<hr/> Signatur		<hr/> Date
43.(1) Every manufacturer of a licensed medical device shall, annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf (a) confirming that all the information and documents supplied by the manufacturer with respect to the device are still correct; or (b) describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1 (2) If the manufacturer fails to comply with subsection (1), the Minister may cancel the medical device licence. (3) If the holder of a medical device licence discontinues the sale of the medical device in Canada, the licensee shall inform the Minister within 30 days after the discontinuance, and the licence shall be cancelled at the time that the Minister is informed.		
Return to: Licence Renewal Medical Devices Bureau Health Products and Food Branch 150 Tunney's Pasture Driveway Room 1605, Main Building Address Locator 0301H1 Ottawa Ontario K1A 0K9 Canada		

RETURN TO BUREAU

Medical Devices Licence Renewal Form

Therapeutic Products Directorate
Medical Devices Bureau

Manufacturer

Choose 1 column below only

Renew All this Page	Discontinue All this page	Discontinue only licenses checked	Licence Number	Licence Name	Class

Appendix 2: Sample Reduced Right to Sell Fee Request and Certification Form

2011

Complete only if you qualify for the reduced fee for the right to sell. Only one manufacturer can be included on each form. Do not submit payment with this form. The returned renewal form and request for reduced fee will be assessed and an invoice based on this assessment will be mailed to you. Fees payable for the right to sell in the year 2011-2012 are \$330 (CDN\$) per licence unless you qualify for a reduced fee. To qualify, you must meet the criteria below.

Eligibility for Reduced Fee

In accordance with subsection 48 (1) of the *Fees in Respect of Drugs and Medical Devices Regulations*, a manufacturer is eligible for a reduced fee for the right to sell if the annual gross revenue (CDN\$), for sales in Canada, from a licensed medical device along with any other medical devices in the same medical device family during the previous calendar year was less than \$20,000 (CDN\$). The reduced fee in 2011 is \$50.00.

Please list below, medical device licenses meeting this criteria.

Licence Number	Total Sales	Previous Calendar Year (Can\$)	Licence Number	Total Sales	Previous Calendar Year (Can\$)

Listing Continued on next page	Yes <input type="checkbox"/>	No <input type="checkbox"/>					
--------------------------------	------------------------------	-----------------------------	--	--	--	--	--

Total # of Licences listed on all pages: _____

x\$50

=

Please note:

In accordance with subsection 49(1) of the *Fees in Respect of Drugs and Medical Devices Regulations*, if the Minister determines that the information provided on the "Reduced Right to Sell Fee and Certification Form" is not adequate to determine the manufacturer's annual gross revenue, the Minister may require the manufacturer to submit sales records that have been audited by a qualified independent auditor and those records shall be used for the purpose of determining the fee payable.

Certification In accordance with subsection 48 (1) of the *Fees in Respect of Drugs and Medical Devices Regulations*

Manufacturer's completed calendar year ending before November 1st (dd/mm/yy): _____

I, the undersigned, being the person responsible for the manufacturer's financial affairs, certify the enclosed information on the annual gross revenue, for sales in Canada, for the licensed medical devices, is true and correct for this firm's previous completed calendar year, as specified below.	
Company Name:	Date:
Signature's Name:	Telephone:
Signature:	Fax:
Title:	
Questions concerning fee deduction- Please contact Finance Unit	