Health Canada
Santé Canada

Health Canada
Resource Management and Operations Directorate
Office of Submissions and Intellectual Property
Finance Building, Address Locator 0201A1
101 Tunney's Pasture Driveway
Ottawa, ON K1A 0K9

June 2021

To All DIN Holders:

Subject: 2021 Annual Drug Renewal Notification

The annual renewal process is required to comply with section C.01.014.5 of the *Food and Drug Regulations* (the Regulations) which requires a DIN holder to confirm annually, before October 1, the current status of all their active DINs and that all information previously submitted with respect to their drug products is correct. The Office of Submissions and Intellectual Property (OSIP) is responsible for preparing and distributing packages including the Annual Drug Notification Form (ADNF) for the annual renewal process to all DIN holders.

The 2021 ADNF is included separately in the email. The annual package is included following the cover letter.

We appreciate your cooperation in returning the ADNF by email at hc.annual-annuelle.sc@canada.ca by July 30, 2021, regardless of whether or not there is any change to the existing information.

The invoices for the Right to Sell Drugs fees will be prepared based on the information in the Drug Product Database on September 30, 2021.

Health Canada has started to send the invoices for the Drug Right to Sell fees using the electronic billing (e-billing) system. Therefore, regular mail will no longer be used for invoices. Invoices are e-billed from the Health Canada's financial system to the designated email address as notified for the Billing contact (A3) section of the ADNF.

If you have not already enrolled in the e-billing program, please submit the completed enrolment form with your ADNF by email to hc.annual-annuelle.sc@canada.ca by July 30, 2021. Companies that have not enrolled in e-billing will have their invoices sent to the billing contact via eFax.

Sincerely,

Anne Bowes
Director
Office of Submissions and Intellectual Property (OSIP)

Canada

2021 ANNUAL PACKAGE

Table of Contents

Information on the Drug Right to Sell Fees for 2021

The annual drug right to sell fees for Human (Disinfectant, Non-prescription drug, or Prescription drug) and Veterinary drug products for which a drug identification number has been assigned under section C.01.014.2 (1) of the *Food and Drug Regulations*, for the billing period from October 1, 2021 to September 30, 2022 are as below:

Fees for Right to Sell Drugs for Human Use **— Schedule 6**		
Fee Category	**Section in *Fees in Respect of Drugs and Medical Devices Order*.**	**Fee as of April 1, 2021**
Disinfectant	52	$1,342
Non-Prescription	52	$2,018
Drug other than one referred to in item 1 or 2 (above)	52	$2,749

Fees for Right to Sell Drugs for Veterinary Use **— Schedule 7**		
Fee Category	**Section in *Fees in Respect of Drugs and Medical Devices Order*.**	**Fee as of April 1, 2021**
Veterinary Drug	56	$367

Instructions for the Completion of the Annual Drug Notification Form

These instructions supplement the *Guidance Document: Fees for the Right to Sell Drugs* and explain how to accurately complete the Annual Drug Notification Form (ADNF).

The ADNF lists all of the manufacturer's drug products with an active Drug Identification Number (DIN). An active DIN is a DIN for a drug product that has been authorized for sale in Canada, and:

- Has never been sold in Canada (Approved); or,
- Is currently being sold in Canada (Marketed); or,
- Was sold in Canada, but has not had a sale for a period of 12 consecutive months (Dormant).

The ADNF is required to comply with section C.01.014.5 of the *Food and Drug Regulations* (the Regulations) which requires a DIN holder to confirm annually, before October 1, the current status of all their active DINs and that all information previously submitted with respect to their drug products is correct.

Please return the signed ADNF by email at hc.annual-annuelle.sc@canada.ca whether or not any changes have been made to the existing information, by July 30, 2021.

- Do not send your payment with the completed ADNF. You will receive an invoice in October. For more information on the payment of fees, refer to section 2.2 of the *Guidance Document: Fees for the Right to Sell Drugs*.
- Do not send your Regulatory Enrolment Process (REP) Company XML file with the completed ADNF. The REP Company file must only be provided via the Common Electronic Submission Gateway (CESG) as per the section 2.3 of the REP Guidance document.

INSTRUCTIONS

The ADNF must be signed and dated by the manufacturer, or by any one of the contacts indicated on the ADNF. If someone who is not listed as a contact on the ADNF signs and dates the ADNF, the manufacturer must provide a letter of authorization confirming that the person who completed the form is authorized to do so.

MITIGATION MEASURES

Drug right to sell fees can be requested to be reduced or waived. To be considered for fee mitigation, manufacturers must apply by indicating the type of mitigation requested on the Annual Drug Notification Form. In the case of small businesses, manufacturers will be required to register online as a small business and ensure that their registration information is accurate and current.

For more information, please consult section 2.3 Mitigation measures of the *Guidance Document: Fees for the Right to Sell Drugs*

The following mitigation measures are available:

Small Business:

Step 1: Register online using the Drug and Medical Device Small Business Application and ensure that the registration information is kept up to date. You should hold a valid small business status at the time of invoicing in October 1st.

- Please consult the application for *Small business mitigation for drugs and medical devices: How to apply for small business status*

- Step by step instructions also included on page 11 of this annual package for your information.

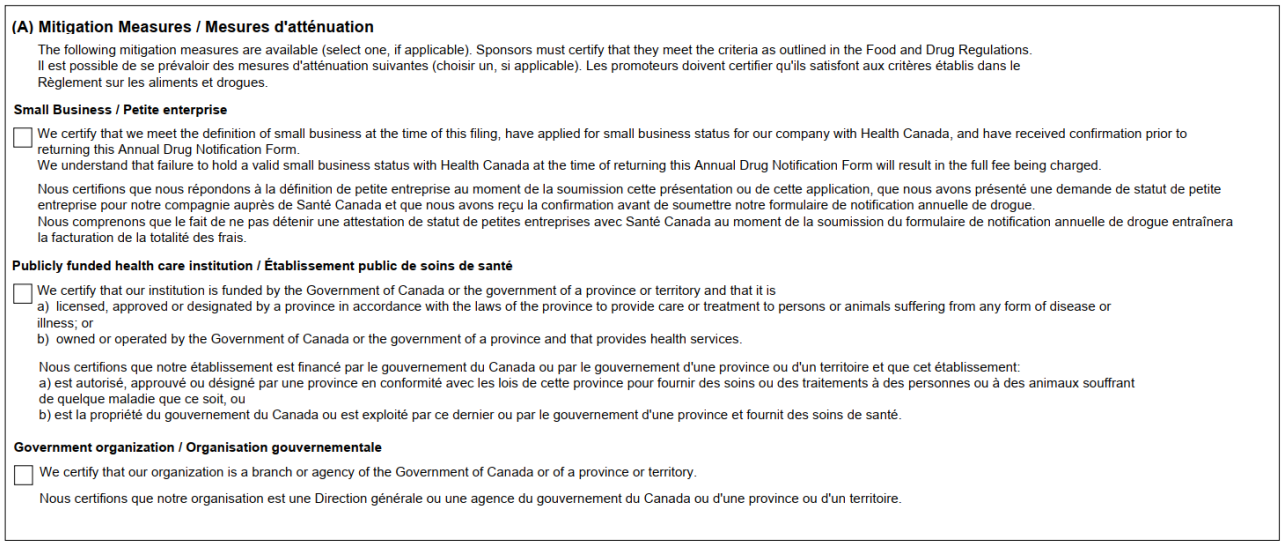
Step 2: Once registered as a small business, this must also be indicated on the ADNF. Check the box for small business on the ADNF, certifying that you meet the definition of small business and have already registered your company with Health Canada prior to submitting the ADNF.

Publicly funded health care institution:

- Check the box on the ADNF if your institution is funded by the Government of Canada or the government of a province or territory

Government organization:

- Check the box on the ADNF if your organization is a branch or agency of the Government of Canada or of a province or territory



(A) Mitigation Measures / Mesures d'atténuation

The following mitigation measures are available (select one, if applicable). Sponsors must certify that they meet the criteria as outlined in the Food and Drug Regulations.
Il est possible de se prévaloir des mesures d'atténuation suivantes (choisir un, si applicable). Les promoteurs doivent certifier qu'ils satisfont aux critères établis dans le Règlement sur les aliments et drogues.

Small Business / Petite enterprise

☐ We certify that we meet the definition of small business at the time of this filing, have applied for small business status for our company with Health Canada, and have received confirmation prior to returning this Annual Drug Notification Form.
We understand that failure to hold a valid small business status with Health Canada at the time of returning this Annual Drug Notification Form will result in the full fee being charged.

Nous certifions que nous répondons à la définition de petite entreprise au moment de la soumission cette présentation ou de cette application, que nous avons présenté une demande de statut de petite entreprise pour notre compagnie auprès de Santé Canada et que nous avons reçu la confirmation avant de soumettre notre formulaire de notification annuelle de drogue.
Nous comprenons que le fait de ne pas détenir une attestation de statut de petites entreprises avec Santé Canada au moment de la soumission du formulaire de notification annuelle de drogue entraînera la facturation de la totalité des frais.

Publicly funded health care institution / Établissement public de soins de santé

☐ We certify that our institution is funded by the Government of Canada or the government of a province or territory and that it 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.

Nous certifions que notre établissement est financé par le gouvernement du Canada ou par le gouvernement d'une province ou d'un territoire et que cet établissement:
a) est autorisé, approuvé ou désigné par une province en conformité avec les lois de cette province pour fournir des soins ou des traitements à des personnes ou à des animaux souffrant de quelque maladie que ce soit, ou
b) est la propriété du gouvernement du Canada ou est exploité par ce dernier ou par le gouvernement d'une province et fournit des soins de santé.

Government organization / Organisation gouvernementale

☐ We certify that our organization is a branch or agency of the Government of Canada or of a province or territory.

Nous certifions que notre organisation est une Direction générale ou une agence du gouvernement du Canada ou d'une province ou d'un territoire.

ADDITIONAL COLLECTION OF INFORMATION:

In addition to the annual renewal process, Health Canada is taking this opportunity to collect additional information from companies in advance for a number of upcoming regulatory activities.

We are collecting the following information in parallel with the annual process:

1. Canada Revenue Agency (CRA) Business Number for the Canadian DIN Holder

Business Numbers (BN) are a nine-digit standard identifier issued by the Canada Revenue Agency (CRA) to be used to simplify interactions between businesses and government services. The Government of Canada is expanding the use of the BN to all services to do business. Moving forward, the BN will be the standard identifier for all Government of Canada business services in order to reduce red tape and provide easier, faster and smarter service delivery.

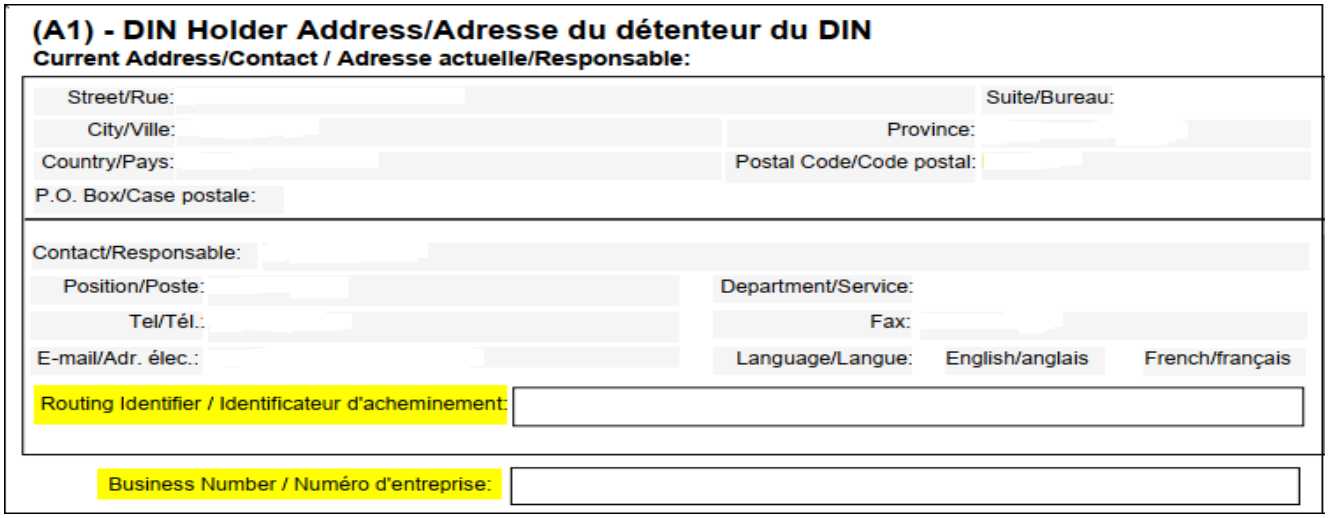
The government's transition to the BN as the standard identifier for business is an essential step towards more efficient digital self-service, supporting a 'single window' and a 'tell us once' approach. If you do not already have a business number you can obtain one from the Canada Revenue Agency. (https://www.canada.ca/en/revenue-agency/services/tax/businesses/topics/registering-your-business/register.html).

2. Routing Identifier:

The routing identifier is a unique identifier within the Common Electronic Submissions Gateway (CESG) used to identify specific gateway accounts, whether it uses the Applicability Statement 2 (AS2) or WebTrader interfaces.

- For the WebTrader users, the routing identifier is automatically assigned to each account by the system. It can be retrieved from the receipt message. Navigate to the WebTrader Inbox, click on "Receipt", "View" document. Document Content page opens up and the routing identifier can be found under attribute: "X-Cyclone-To:"
- For the AS2 users, the routing identifier has to be created by the company. It is recommended that the company's data universal numbering system number be used, but any alpha-numeric text string is acceptable.

The routing identifier will eventually be used for 2-way communication between sponsors and Health Canada over the CESG. In the interim, Health Canada will continue to collect routing IDs on a voluntary basis.



(A1) - DIN Holder Address/Adresse du détenteur du DIN

Current Address/Contact / Adresse actuelle/Responsable:

Street/Rue:		Suite/Bureau:	
City/Ville:		Province:	
Country/Pays:		Postal Code/Code postal:	
P.O. Box/Case postale:			
Contact/Responsable:			
Position/Poste:		Department/Service:	
Tel/Tél.:		Fax:	
E-mail/Adr. élec.:		Language/Langue:	English/anglais French/français
Routing Identifier / Identificateur d'acheminement:			
Business Number / Numéro d'entreprise:			

COMPANY INFORMATION:

The company information in the ADNF includes the address and contact information for below:

(A1) – DIN Holder Address
(A2) – Annual Notification Address
(A3) – Billing Address
(A4) – Other Importer Address

Use of *Regulatory Enrolment Process* (REP) to update information has been mandatory as of October 1, 2020 for pharmaceuticals, biologics and radiopharmaceuticals for human use, as well as disinfectants. It is also available for voluntary use as of May 3, 2021 for veterinary drugs. Detailed information regarding the REP is available on the REP information page.

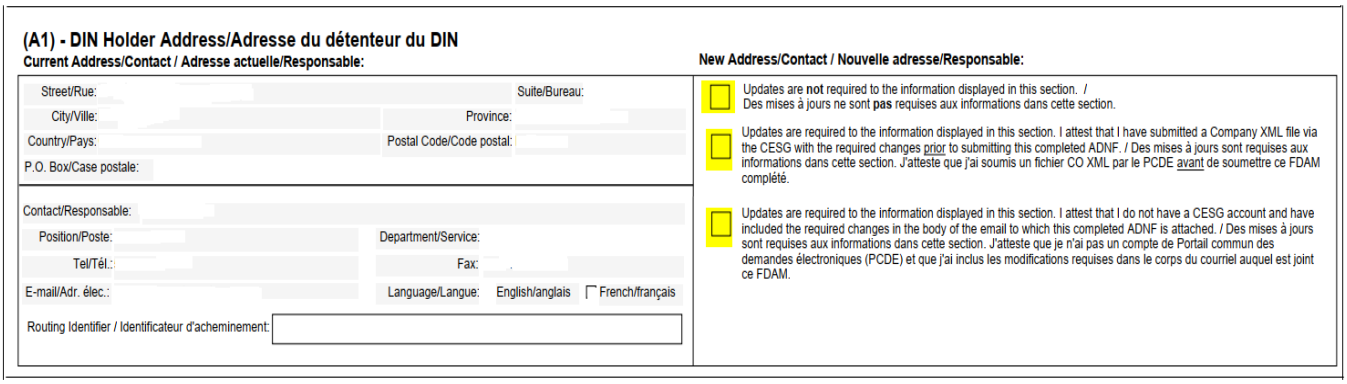
To streamline the process, the option to provide any update to a company information directly in the "New Address/Contact" section of the ADNF has been removed.

Options are available instead in the "New Address/Contact" section to indicate any update to the company information, depending on whether your company has a Common Electronic Submissions Gateway (CESG) account or not.

Options included in the ADNF are as below:

- ☐ Updates are **not** required to the information displayed in this section.
- ☐ Updates are required to the information displayed in this section. I attest that I have submitted a Company XML file via the CESG with the required changes prior to submitting this completed ADNF.
- ☐ Updates are required to the information displayed in this section. I attest that I do not have a CESG account and have included the required changes in the body of the email to which this completed ADNF is attached.

Please refer to Section 2.3 of the Guidance Document: The Regulatory Enrolment Process (REP) for further instructions on how to submit a Company XML file via the Common Electronic Submissions Gateway (CESG).



(A1) - DIN Holder Address/Adresse du détenteur du DIN

Current Address/Contact / Adresse actuelle/Responsable:

Street/Rue: Suite/Bureau:
City/Ville: Province:
Country/Pays: Postal Code/Code postal:
P.O. Box/Case postale:

Contact/Responsable:
Position/Poste: Department/Service:
Tel/Tél.: Fax:
E-mail/Adr. élec.: Language/Langue: English/anglais French/français
Routing Identifier / Identificateur d'acheminement:

New Address/Contact / Nouvelle adresse/Responsable:

Updates are **not** required to the information displayed in this section. /
Des mises à jours ne sont **pas** requises aux informations dans cette section.

Updates are required to the information displayed in this section. I attest that I have submitted a Company XML file via the CESG with the required changes prior to submitting this completed ADNF. / Des mises à jours sont requises aux informations dans cette section. J'atteste que j'ai soumis un fichier CO XML par le PCDE avant de soumettre ce FDAM complété.

Updates are required to the information displayed in this section. I attest that I do not have a CESG account and have included the required changes in the body of the email to which this completed ADNF is attached. / Des mises à jours sont requises aux informations dans cette section. J'atteste que je n'ai pas un compte de Portail commun des demandes électroniques (PCDE) et que j'ai inclus les modifications requises dans le corps du courriel auquel est joint ce FDAM.

Companies with CESG (Common Electronic Submission Gateway) account:

Check the appropriate box on the ADNF for company information and process as below.

- If there are no company information changes, then the REP Company XML file does not need to be amended or sent to Health Canada.

  Submit the signed ADNF by email.

- If you are updating your company information, all changes must be submitted using the REP Company XML file via CESG as per the instructions detailed in section 2.3 of the REP Guidance Document. Do not send your ADNF via the CESG.

    - If you are submitting the REP Company XML file for the first time to update your company information, you must include the Company code in the 'Reason for Filing' box of the REP Company template.

  Submit the signed ADNF by email.

Companies without CESG (Common Electronic Submission Gateway) account:

Check the appropriate box on the ADNF for company information and process as below.

- If there are no company information changes,

  Submit the signed ADNF by email.

- If you are updating your company information, and your company does not have a CESG account, provide the required changes in the body of the email to which the completed ADNF is attached.

  Submit the signed ADNF and the updated information in one email.

Section (A1) - DIN Holder (Registered manufacturer) Address:

Please provide a single address belonging to the company at which the manufacturer contact person is located. Note also that Section C.01.014.4 of the Regulations requires the manufacturer to provide Health Canada with written notice of an address change within 30 days of the change.

Note that a substantive change to the manufacturer company name requires the filing of an administrative application in accordance with the *Guidance Document Administrative Processing of submissions applications: Humans or Disinfectant Drugs*.

Section (A2) - Annual Notification Address:

The name and address of the company to which the manufacturer wishes the ADNF to be sent.

Note that only one ADNF can be issued for each manufacturer and, therefore, only one annual notification address will be recorded.

Where different divisions within a company are responsible for different product portfolios, a single contact is expected to be responsible for coordinating the return of the complete ADNF.

Section (A3) - Billing Address:

The company and address to which the manufacturer wishes Health Canada to send invoices pertaining to annual fees charged under the:

- *Fees in Respect of Drugs and Medical Devices Order, Division 4: Fees for Right to Sell Drugs for human use*; and,
- *Fees in Respect of Drugs and Medical Devices Order, Division 5: Fees for Right to Sell Drugs for Veterinary Use Only.*

Health Canada has started to send the invoices for the Drug Right to Sell fees using the electronic billing (e-billing) system. Invoices are e-billed from the Health Canada's financial system to the designated email address as notified for the Billing contact (A3) section of the ADNF.

Companies that have not enrolled in e-billing will have their invoices sent to the billing contact via eFax.

Section (A4) - Other Importer Address:

The Canadian importer is the company in Canada that is authorized by the manufacturer to take legal responsibility for the drug products, which are owned by the manufacturer located in a foreign country.

This should be completed only if the DIN holder address in A1 is not in Canada and if the Canadian importer(s) has/have not been identified in A2 or A3. The importer information is mandatory for manufacturers located outside of Canada.

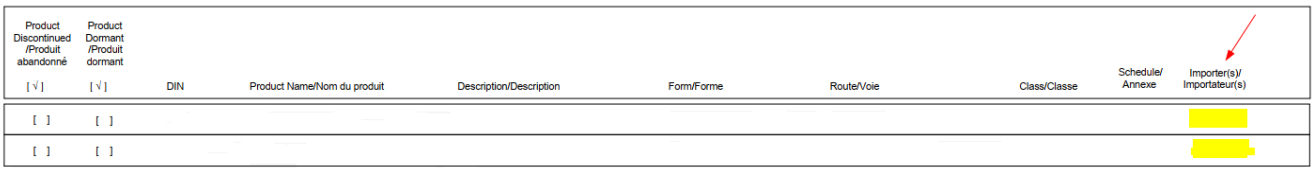
If more than one Canadian importer is authorized by the manufacturer, please provide the required information for each importer in the body of the email to which the completed ADNF is attached. The new information will appear in Other Importer Address blocks (e.g. A4, A5, A6 etc.) of the ADNF for the following year.

Note that the sub-section C. 01.014.4(b) of the Regulations requires the manufacturer to provide Health Canada with written notice of any changes to the importer(s) or to the importer's address within 30 days of the change.

Importer for Each Drug Product:

For manufacturers located outside of Canada, an importer must be listed for each marketed drug product. The Canadian importer is authorized by the non-Canadian manufacturer to accept legal responsibility for the listed drug products.

Identify the importer for each drug product by referencing the applicable address block (e.g. A2, A3, A4 etc.) in the "Importer" field beside each drug product.



Product Discontinued /Produit abandonné [√]	Product Dormant /Produit dormant [√]	DIN	Product Name/Nom du produit	Description/Description	Form/Forme	Route/Voie	Class/Classe	Schedule/ Annexe	Importer(s)/ Importateur(s)
[ ]	[ ]								
[ ]	[ ]								

DRUG PRODUCT INFORMATION:

Drug Product List:

The drug product list includes all active DINs (i.e., DINs with an Approved, Marketed, or Dormant status in the DPD) and the corresponding information for each drug product. The information is taken from the DPD, and is current as of the date and time that the ADNF is generated.

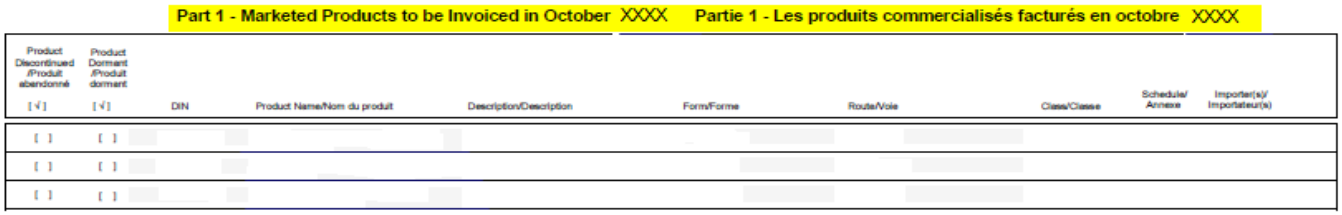
The drug product list is divided into 4 separate parts.

Part 1 - Marketed Products to be invoiced in October:

All drug products (including Schedule C drugs) that are marketed in Canada and will be invoiced on October 1st. The Right to Sell Fees for human and veterinary drugs will be invoiced as per the *Fees in Respect of Drugs and Medical Devices Order*.

Confirm the status of each drug product on the ADNF:

- If the status of your drug product is still Marketed, do not check any boxes.
    - Reminder: for additional packaging sizes of already marketed DINs, **do not** submit additional **market notification**.
- If you have not sold your drug product for at least 12 consecutive months, check the box "Product Dormant".
- If a decision has been made to stop selling your drug product, check the box "Product Discontinued" and complete the *Form: Discontinuation of Drugs Sales* attached to this package.



Part 1 - Marketed Products to be Invoiced in October XXXX Partie 1 - Les produits commercialisés facturés en octobre XXXX

Product Discontinued /Produit abandonné [√]	Product Dormant /Produit dormant [√]	DIN	Product Name/Nom du produit	Description/Description	Form/Forme	Route/Voie	Class/Classe	Schedule/ Annexe	Importer(s)/ Importateur(s)
[ ]	[ ]								
[ ]	[ ]								
[ ]	[ ]								

Part 2 - Marketed Products with deferred fees: NO LONGER APPLICABLE.

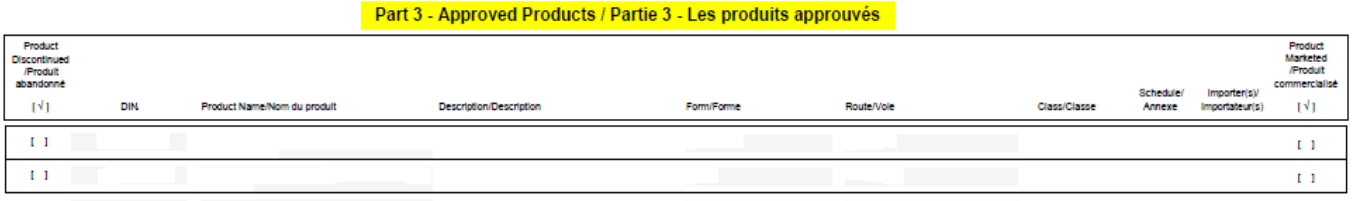
As per Division 4, Section 52 (2) of the *Fees in Respect of Drugs and Medical Devices Order* Health Canada will no longer defer fees for manufacturers that have not completed their first full fiscal year of sale.

Part 3 – Approved Products:

This section pertains to all drug products that are approved for sale but not yet marketed in Canada.

Confirm the status of each drug product on the ADNF:

- If the status of your drug product is still Approved, do not check any boxes.
- If you sold your drug product, please check the box in the last column "Product Marketed" and submit, as per the **usual process**, your market notification (**i.e., Drug Notification Form and labels, when applicable**).
    - For the instructions on how to submit a complete market notification, refer to the *Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs)*.
- If you made the decision to not market your drug product and discontinue it, check the box in the first column "Product Discontinued".



Part 3 - Approved Products / Partie 3 - Les produits approuvés

Product Discontinued /Produit abandonné [√]	DIN	Product Name/Nom du produit	Description/Description	Form/Forme	Route/Voie	Class/Classe	Schedule/ Annexe	Importer(s)/ Importateur(s)	Product Marketed /Produit commercialisé [√]
[ ]									[ ]
[ ]									[ ]

Part 4 – Dormant Products:

This section pertains to all drug products that were marketed in Canada but have not had any sales for at least 12 consecutive months.

Confirm the status of each drug product on the ADNF:

- If the status of your drug product is still Dormant, do not check any boxes.

- If you have reintroduced your drug product on the market, please check the box in the column "Product Marketed" and submit as per the **usual process**, your **market notification**.

    - Your DNF should include the date of reintroduction after the period of dormancy.
    - Marketed labels for a drug that is marketed after a period of dormancy are not required with the DNF.

- If you made the decision to discontinue your drug product, please check the box in the first column "Product Discontinued" and complete the *Form: Discontinuation of Drugs Sales* attached to this package.

Part 4 - Dormant Products / Partie 4 - Les produits dormants

Product Discontinued /Produit abandonné [√]	DIN	Product Name/Nom du produit	Description/Description	Form/Forme	Route/Voie	Class/Classe	Schedule/ Annexe	Importer(s)/ Importateur(s)	Product Marketed /Produit commercialisé [√]
[ ]									[ ]

All drug product lists – Confirming product information other than status

- Product names longer than 45 characters may have been abbreviated.

- Only non-substantive changes to a product name may be registered through the annual notification process, e.g., spelling error.

- For a substantive name change, a new application or submission must be filed with Health Canada as per sub-section C.01.014.4 (a) of the Regulations.

- The route of administration, dosage form, schedule and class should not be changed.
  A new application or submission must be filed with Health Canada.

How to apply for or renew Small Business status

You can apply for or renew small business status through the Drug and Medical Device Small Business Application. If this is your first time applying for small business status, there are a few steps you must follow to create your initial small business profile and submit your application.

To receive small business status please follow these steps:

1. Determine your unique identifier
    a. For information on how to determine your identifier please visit the following link: https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/small-business-mitigation/before-apply.html

2. Receive and return a completed Trading Partner Profile from hc.tpmo-bgpc.sc@canada.ca
    a. Please note that while it is necessary to mail a copy of the Trading Partner Profile to the Trading Partner Management Office, **emailing a scanned copy to the above email address** will allow the TPMO to provide you with your activation code upon processing of your email.

3. Receive an activation code from hc.tpmo-bgpc.sc@canada.ca

4. Create a GCKey or Sign-in Partner (if you do not already have one)
    a. Please use the following link: https://dmdsba-apemim.hc-sc.gc.ca/app/

5. Log in to your GCKey or Sign-in Partner account and enter your activation code
    a. Please use the following link: https://dmdsba-apemim.hc-sc.gc.ca/app/

6. Access the Drug and Medical Device Small Business Application and submit your small business application
    a. Requested information will be submitted through the application.

Further information on the small business status application process **is available on the Funding and Fees webpage**.

If you have any further questions, please contact the **Small Business Office** at hc.sbo-bpe.sc@canada.ca.

Instructions for completion of the Enrolment Form for Electronic Billing (E-Billing) for the Drug Right to Sell fees

Health Canada has started to send the invoices and statements for the Drug Right to Sell (DRTS) fees using the electronic billing (e-billing) system; therefore, regular mail will no longer be used for invoices.

If you have not already enrolled in the e-billing program, please submit the completed enrolment form with your ADNF by email to hc.annual-annuelle.sc@canada.ca by July 30, 2021.

Companies that have not enrolled in e-billing will have their invoices sent to the billing contact via e-Fax.

A blank enrolment form is attached in Appendix A of this annual package. Below is a sample form with instructions (in red font) on how to complete the enrolment form for e-billing.

Note: the e-billing enrolment form only needs to be completed one time.

- If any of the information provided on this form has changed, please submit the changes on the company template as part of the Regulatory Enrolment Process (REP) via the Common Electronic Submission Gateway (CESG). If you do not have a CESG account, submit the required changes to the Client information Unit by email at hc.client.information.sc@canada.ca.

- If you wish to unsubscribe from e-billing, please email hc.client.information.sc@canada.ca.

Sample enrolment form with instructions in red font:

Health Canada Santé Canada

Company Code: **<** Enter the DPD Code/Company ID for the DIN Holder **>**

Company Name: **<** Enter the name of the **DIN Holder >**

RE: Notification of Electronic Billing

In an effort to reduce paper consumption, Health Canada would like to inform/remind all customers that we now offer electronic billing. We can now send invoices/statements to you by email. In light of this development, Health Canada now offers two alternatives to receiving your invoices/statements:

1. **Via Electronic:** We believe this method of delivering invoices/statements is fast, efficient and cost effective. To receive your invoices/statements via electronic means, please complete the attached form and return it to us. Please note that upon submission of this enrolment form to Health Canada by return, Health Canada will transmit your invoices/statements to you only via electronic mail and all other paper mailings will cease.

2. **Via Regular Mail:** Although this method of delivering invoices/statements is slower and not "environmentally friendly", by not completing the following form indicates that you prefer to continue to receive your invoices/statements via mail.

Enrolment in Electronic Transmission of Electronic Billing:

1. The undersigned customer ("Customer") hereby agrees to receiving invoices/statements relating to the undersigned's account(s) with Health Canada by electronic media rather than by hard copy mailing and hereby requests that Health Canada transmit to Customer such invoices/statements solely by electronic mail at the address designated below. Customer acknowledges that the information in the email message and invoice attached as a pdf file will be in clear text and will not be encrypted or otherwise protected or secured during transmission. Should the email be received or intercepted by a third party unintended recipient the contents of the email and invoice could be read.

2. An invoice by email will serve as the original invoice

3. Customer understands that invoices/statements from Health Canada will be automatically sent to the email address provided by the customer below.

4. Customer will be responsible for retaining sufficient and adequate copies of the invoices for its internal record keeping requirements.

5. Customer acknowledges to have received each e-mail billing unless Health Canada receives a notification that the email did not reach its intended recipient and the records of Health Canada shall be conclusive in this regard.

6. Health Canada does not accept any liability for any errors or omissions in the email address provided by the Customer. Health Canada does not accept any liability for information not delivered or delivered to or intercepted by a third party unintended recipient.

7. Customer understands that it must have a valid e-mail address.

8. Customer understands that it must have software allowing for viewing of .pdf files.

Sold to:	**Bill to:**
< Enter the address for the **DIN Holder >** **This **must** be the **same address** as section **A1** of the ADNF. **If it is not the same, the changes must also be sent using the company (CO) XML file using the REP.** **Note**: Statements will be sent to the email address of the **DIN Holder**.	**<** Enter the address for the **Billing Contact >** ** This **must** be the **same address** as section **A3** of the ADNF. **If it is not the same, the changes must also be sent using the company (CO) XML file using the REP.** **Note**: Invoices will be sent to the email address of the **Billing Contact**.

Required information (TYPEWRITTEN or PRINT CLEARLY IN UPPERCASE LETTERS):

Subscribe to eBilling: ☐ Unsubscribe to eBilling: ☐ Email address change: ☐

< Enter the email address for the **Billing Contact > **** It **must** be the same email as listed in section **A3** of the ADNF. **If it is not the same, the changes must also be sent using the company (CO) XML file using the REP.**

_____

E-mail address to which electronic **invoices** are to be sent

< Enter the email address for the **DIN Holder > **** It **must** be the same email as listed in section **A1** of the ADNF. **If it is not the same, the changes must also be sent using the company (CO) XML file using the REP.**

_____

E-mail address to which electronic **statements** are to be sent

(Insert Company name)_____ **<** Enter the name of the **DIN Holder >** _____hereby requests all invoices to be sent to the above-noted email address and agrees to all of the above terms and conditions.

_____

Signature of duly authorized representative

Name and title of authorized representative: _____ (fill in)

Phone number: _____ Date: _____

Please email your completed form to:

Email: hc.annual-annuelle.sc@canada.ca

Appendices

Health Canada Santé Canada

Company Code:
Company Name:

RE: Notification of Electronic Billing

In an effort to reduce paper consumption, Health Canada would like to inform/remind all customers that we now offer electronic billing. We can now send invoices/statements to you by email. In light of this development, Health Canada now offers two alternatives to receiving your invoices/statements:

1. **Via Electronic:** We believe this method of delivering invoices/statements is fast, efficient and cost effective. To receive your invoices/statements via electronic means, please complete the attached form and return it to us. Please note that upon submission of this enrolment form to Health Canada by return, Health Canada will transmit your invoices/statements to you only via electronic mail and all other paper mailings will cease.

2. **Via Regular Mail:** Although this method of delivering invoices/statements is slower and not "environmentally friendly", by not completing the following form indicates that you prefer to continue to receive your invoices/statements via mail.

Enrolment in Electronic Transmission of Electronic Billing:

1. The undersigned customer ("Customer") hereby agrees to receiving invoices/statements relating to the undersigned's account(s) with Health Canada by electronic media rather than by hard copy mailing and hereby requests that Health Canada transmit to Customer such invoices/statements solely by electronic mail at the address designated below. Customer acknowledges that the information in the email message and invoice attached as a pdf file will be in clear text and will not be encrypted or otherwise protected or secured during transmission. Should the email be received or intercepted by a third party unintended recipient the contents of the email and invoice could be read.

2. An invoice by email will serve as the original invoice

3. Customer understands that invoices/statements from Health Canada will be automatically sent to the email address provided by the customer below.

4. Customer will be responsible for retaining sufficient and adequate copies of the invoices for its internal record keeping requirements.

5. Customer acknowledges to have received each e-mail billing unless Health Canada receives a notification that the email did not reach its intended recipient and the records of Health Canada shall be conclusive in this regard.

6. Health Canada does not accept any liability for any errors or omissions in the email address provided by the Customer. Health Canada does not accept any liability for information not delivered or delivered to or intercepted by a third party unintended recipient.

7. Customer understands that it must have a valid e-mail address.

8. Customer understands that it must have software allowing for viewing of .pdf files.

Sold to:	Bill to:

Required information (TYPEWRITTEN or PRINT CLEARLY IN UPPERCASE LETTERS):

Subscribe to eBilling: ☐ Unsubscribe to eBilling: ☐ Email address change: ☐

_____

E-mail address to which electronic **invoices** are to be sent

_____

E-mail address to which electronic **statements** are to be sent

(Insert Company name)_____hereby requests all invoices to be sent to the above-noted email address and agrees to all of the above terms and conditions.

_____

Signature of duly authorized representative

Name and title of authorized representative: _____ (fill in)

Phone number: _____ Date: _____

Please email your completed form to: hc.annual-annuelle.sc@canada.ca

FORM: DISCONTINUATION OF DRUGS SALES
FORMULAIRE: CESSATION DE VENTES DE MÉDICAMENTS

INSTRUCTIONS

- For each drug product with the preceding status of **marketed**, provide the following:
  - DIN and status
  - Discontinuation date (i.e., date of the **last sale** by the manufacturer)
  - Number of last lot distributed; and,
  - Expiration date of last lot distributed

- For each drug product with the preceding status of **dormant** product, provide the following:
  - DIN and status
  - Discontinuation date (i.e., date on which the **decision to permanently discontinue** was made)

    IMPORTANT! The date of discontinuation should fall on a day after the date the DIN was reported to be dormant
  - Number of last lot distributed; and,
  - Expiration date of last lot distributed

INSTRUCTIONS

- Pour chaque produit pharmaceutique ayant été considéré précédemment comme **commercialisé**, veuillez fournir les renseignements suivants :
  - DIN et statut
  - Date de cessation (c.-à-d., date à laquelle le fabricant a réalisé la **dernière vente**)
  - Numéro du dernier lot distribué
  - Date limite d'utilisation du dernier lot distribué

- Pour chaque produit pharmaceutique ayant été considéré précédemment comme **dormant**, veuillez fournir les renseignements suivants :
  - DIN et statut
  - Date de cessation (c.-à-d., date à laquelle la **décision de discontinuer le produit définitivement** a été prise)

    IMPORTANT : La date de cessation doit être postérieure à la date à laquelle le DIN a été déclaré comme dormant.
  - Numéro du dernier lot distribué
  - Date limite d'utilisation du dernier lot distribué

COMPANY CODE/CODE DE LA SOCIÉTÉ: DPD _____

DIN(s)	**DISCONTINUATION DATE** (YYYY/MM/DD) **DATE DE CESSATION** (AAAA/MM/JJ)	**NUMBER OF LAST LOT DISTRIBUTED** **NUMÉRO DU DERNIER LOT DISTRIBUÉ**	**EXPIRATION DATE OF LAST LOT DISTRIBUTED** (YYYY/MM/DD) **DATE LIMITE D'UTILISATION DU DERNIER LOT DISTRIBUÉ** (AAAA/MM/JJ)

Name/Nom: _____ Title/Titre: _____

Signature: _____ Date: _____

Canada