Health Products and Food Branch
Inspectorate
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04-104725-188

To: Associations

I am pleased to inform you that the document entitled "Conditions for Provision of Packaging/Labelling Services for Drugs under Foreign Ownership" is now available on the Health Products and Food Branch Inspectorate website at the following address:

www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate

This document has been developed by the Inspectorate and is intended to clarify specific requirements to be met by a Canadian establishment seeking to bring into Canada a shipment of a drug solely to provide contract packaging/labelling services in relation to that drug that is then re-exported to the foreign manufacturer who retains ownership of the drug during such a transaction. Drugs imported outside the scope of this document should meet all applicable requirements under the *Food and Drugs Act and Regulations*.

Inquiries about this document can be addressed to Ms. France Dansereau, Manager, Drug GMP Inspection Unit, by telephone at (613) 957-1492, by fax at (613) 952-9805, or by email at GMP_questions_BPF@hc-sc.gc.ca.

Original signed by
Diana Dowthwaite (for)

Jean Lambert
Director General

Health Products and Food Branch Inspectorate

GUIDE-0067

CONDITIONS FOR PROVISION OF PACKAGING/LABELLING SERVICES FOR DRUGS UNDER FOREIGN OWNERSHIP

Supersedes:	New document
Date issued:	May 1st, 2004
Date of implementation:	July 1st, 2004

Ce document est disponible en français.

Canada

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1.0 PURPOSE

This document clarifies the specific requirements to be met by a Canadian packager / labeller in possession of an Establishment Licence that brings a drug into Canada solely to provide contract packaging/labelling services for that drug, which is then returned to the same fabricator from whom the product was received and who retains ownership of the drug throughout the transaction.

Such drugs:

- **are not** sold in Canada.
- **do not** have a DIN
- **are not** represented as Canadian products
- **are not** sold by the Canadian establishment providing the packaging/labelling service.

If the conditions set forth are met, the Inspectorate will have a degree of confidence to the effect that the drugs received are not imported for sale in Canada in contravention of the *Food and Drug Regulations (FDR)*but rather are being packaged and returned to the fabricator. The Inspectorate may ask for further evidence that the drugs to be packaged are returned to the fabricator.

2.0 BACKGROUND

Under section A.01.040 of the *FDR*, all drugs in dosage form that are imported into Canada for the purpose of sale must comply with the requirements of the Food and Drugs Act (FDA) and *Regulations*, regardless of whether the drug is to be sold to Canadian or to foreign customers. However, it has been recognized that an establishment may wish to import a commercial shipment of a drug that has not been authorized for sale in Canada solely for the purpose of providing a contract packaging/labelling service to a foreign establishment that retains ownership of the drug. Therefore certain conditions must be met in order to ensure that such drugs are not sold by the Canadian establishment and are returned to the foreign fabricator that owns the drug. It should be understood that no Certificate of Pharmaceutical Product (CPP) will be issued for these drugs.

In response to questions from industry pertaining to the requirements that must be met in order for drugs to enter into Canada, the Inspectorate developed a "**Guidance document on the commercial importation and exportation of drugs in dosage forms under the Food and Drugs Act**". Further information is available in this guidance document.

3.0 SCOPE

This document applies to commercial shipments of unapproved drugs in dosage form that are brought into Canada solely for the purpose of providing a packaging/labelling service to the foreign fabricator that owns the drug.

Drugs imported outside the scope of this document should meet all applicable requirements under the *FDA and Regulations*.

This document does not apply to the following:

- drugs imported for personal use
- active pharmaceutical ingredients
- samples of drugs to be tested by a Canadian laboratory
- drugs to be sold in Canada
- drugs represented as Canadian products, such as those bearing a Canadian name, logo, address, or any other Canadian symbol.

4.0 REQUIREMENTS

Drugs may be brought into Canada by a licenced Packager / Labeller for the purpose of providing packaging/labelling services to a foreign fabricator that retains ownership of the drug under the following conditions:

4.1 Ten (10) days prior to each shipment to Canada a notice (see attached annex) is sent by the Canadian contract packager/labeller to Health Canada specifying the following:

- the name of the drug and the quantity that is to be received by the contract packager/labeller
- the lot number of the drug to be received
- the name and address of the foreign owner of the drug
- the name and address of Canadian contract packager/labeller
- the date and port of entry into Canada
- the anticipated date of return of the drug to the foreign owner in the same country of origin.

4.2 Ten (10) days following completion of each packaging/labelling order and the return of the drug to the foreign owner a notice (see attached annex) is sent to Health Canada specifying the following:

- confirmation of the return of the packaged/labelled drug and any bulk unpackaged drug to the same fabricator in the same country from whom it was received
- the quantity returned
- brief description of packaging format(s) returned to owner and copies of labels and any other printed packaging components used to package/label the drug.

4.3 The following information is maintained on the premises of the Canadian contract packager/labeller and will be subject to review at the time of inspection:

- a written and signed contract that specifies the services to be provided and states that the drug remains under the ownership of the foreign establishment and that it is to be returned to the same owner from which it is received
- evidence that the foreign regulatory authority has authorized the

packaging/labelling activity in Canada
- copies of labels and any other printed packaging components used to package/label the drug
- packaging/labelling batch documents for all services provided
- evidence that all quantities of the drug received have been returned to the foreign owner.

4.3.1 The following information must be sent to the Health Products and Food Branch Inspectorate, Drug GMP Inspection Unit, in Ottawa:

- evidence that the foreign establishment that owns the drug is in compliance with applicable GMP requirements. Evidence acceptable is described in the document "Conditions for acceptance of foreign inspection reports for listing foreign sites on Canadian Establishment licence".

4.4 The information required under 4.1 and 4.2 must be sent to the operational centre of the Health Products and Food Branch Inspectorate located in the region of the contract packager/labeller. Please consult the attached list of Operational Centres. Acknowledgement of receipt of the notification will not be issued by the Operational Centre but this information may be verified at any time by an inspector.

4.5 A copy of the information required under 4.1 must also be included with the shipment when it is brought into Canada.

5.0 PERIOD OF RETENTION OF RECORDS

Records required by Section 4.0 of this document must be kept for a period of 1 year after the expiration date on the label of the drug or 4 years after the finished packaged product is returned to its owner if no such date is indicated on the label.

GMP Committee Members

Name	Title / Office / Bureau	Location
France Dansereau, Chair	Manager, Drug GMP Inspection Unit, HPFBI*	Ottawa, ON
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Richard Ferland	MRA officer, HPFBI	Longueuil, QC
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Denis Girard	Scientific Assessment Advisor, VDD***	Ottawa, ON
Raymond Giroux	Drug Specialist, Quebec Operational Centre, HPFBI	Longueuil, QC
Paul Gustafson	Compliance Officer, Manitoba and Saskatchewan Operational Centre, HPFBI	Winnipeg, MB
Grazyna Kujath	Compliance Officer, Atlantic Operational Centre, HPFBI	Halifax, NS
Stephen McCaul	MRA Officer, HPFBI	Toronto, ON
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Sheila Welock	Drug Specialist, Western Operational Centre, HPFBI	Burnaby, BC

* Health Products and Food Branch Inspectorate
** Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate
*** Veterinary Drugs Directorate, Health Products and Food Branch
**** Biologics and Genetic Therapies Directorate

Health Products and Food Branch Inspectorate
Operational Centres

ATLANTIC OPERATIONAL CENTRE
1505 Barrington Street, Suite 1625
Halifax, Nova Scotia, B2J 3Y6
Manager:
T 902 426 5350
F 902-426-6676

QUEBEC OPERATIONAL CENTRE
1001 West St-Laurent Blvd.
Longueuil, Québec, J4K 1C7
Manager:
T 450-646-1353
F 450-928-4455

ONTARIO OPERATIONAL CENTRE
2301 Midland Avenue
Scarborough, Ontario, M1P 4R7
Manager:
T 416-973-1600
F 416-973-1954

MANITOBA AND SASKATCHEWAN OPERATIONAL CENTRE
510 Lagimodière Blvd.
Winnipeg, Manitoba, R2J 3Y1
Manager:
T 204-984-1341
F 204-984-2155

WESTERN OPERATIONAL CENTRE
4595 Canada Way, 4th floor
Burnaby, British Columbia, V5G 1J9
Manager:
T 604-666-3704
F 604-666-3149

DRUG GMP INSPECTION UNIT
Graham Spry Building, 2nd floor
250 Lanark Avenue
P.L. 2002B
Ottawa, Ontario, K1A 0K9
Manager:
T 613-957-1492
F 613-952-9805

Annex / Annexe : Notification Form / Formulaire de notification

Part 1/ Partie 1 **Notification to Health Canada prior to shipment to Canada /** **Notification à Santé Canada avant l'envoi au Canada**	
Contract packager-labeller	Emballeur/étiqueteur contractuel
Name / Nom : Address / Adresse : City / Ville, Province : Postal Code / Code postal : Telephone / Téléphone : Fax :	
Drug to be packaged/labelled	Drogue à être emballée/étiquetée
Name (active ingredient) / Nom (ingrédient actif) : Brand name / Nom de marque : Quantity / Quantité : Manufacture date / Date de fabrication :	
Foreign fabricator	Manufacturier étranger
Name / Nom : Address / Adresse : City / Ville : Country / Pays :	
Expected date of entry into Canada	Date prévue d'entrée au Canada
Port of entry in Canada	Port d'entrée au Canada
Expected date of return to the fabricator	Date prévue de retour au manufacturier étranger
Part 2/ Partie 2 **Notification to Health Canada after the return of the drug to the foreign owner /** **Notification à Santé Canada après l'expédition de la drogue au propriétaire étranger**	
Quantity packaged Type and format of packaging material Quantity of drug per packaging unit Number of units packaged	Quantité emballée Type et format du matériel d'emballage Quantité de drogue / unité d'emballage Nombre d'unités emballées
Quantity of packaged units returned to the fabricator Date of return Transport Mode	Nombre d'unités emballées retournées au manufacturier Date de retour Moyen de transport
If discrepancies, please explain:	Si différence, svp expliquez
Signature :	