Therapeutic Products Directorate
Tunney's Pasture
Address Locator # 0702A
OTTAWA, Ontario
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July 25, 1997

97-022747

Attached List

Please find attached the Directive from the Therapeutic Products Programme, **Assignment of Drug Identification Numbers for Drug Products in Kits** for your review and comments.

Although the regulatory requirements for drug products sold in kits are identical to those for other drug products sold in Canada, the lack of a policy to provide guidance for these products has generated frequent enquiries. This policy was developed to ensure consistency with respect to DIN assignment for this presentation of drug product.

The scope of the policy covers all drug products sold in kits for use in humans, with the exception of drugs mentioned or described in Schedule C to the *Act* (radiopharmaceutical products).

The electronic form of this policy will be available on our website at http://www.hc-sc.gc.ca/hpb-dgps/therapeut. This notice is being distributed to manufacturers of drug products in kits and kit assemblers as well as the drug and medical device industry associations in Canada.

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Reassignment of DINs as a direct result of this policy will not be subject to a cost recovery submission fee.

We would appreciate your comments on the policy and the potential impact it will have on your company. Please forward your comments to the DIN Submission Evaluation Section, Submission Management Division, Bureau of Pharmaceutical Assessment, Holland Cross, Tower B, 2nd Floor, 1600 Scott Street, Address Locator 3102D, Ottawa, Ontario, K1A 1B6 (Fax 613-941-1668) by September 1, 1997.

Original signed by

Dann M. Michols
Director General

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DIRECTIVE **July 21, 1997**
From the Therapeutic Products Programme **970721.ext**

Assignment of Drug Identification Numbers for Drug Products in Kits

Purpose

This policy describes the requirements relating to the assignment of Drug Identification Numbers (DINs) for drug products sold in kits in accordance with the Canadian *Food and Drug Act and Regulations (FDA&R).*

Background

Kits containing drug products are available in many presentations containing different types of medications, sometimes in combination with non-drug products. As kits containing drug products are unique with respect to DIN assignment and labelling, determination of their regulatory requirements has proven to be complicated. The lack of a policy to provide guidance for these products has generated periodic enquiries to the Therapeutic Products Programme. The directive described below was developed to provide consistency to the assignment of DINs to drug products sold in kits, and to ensure that the Canadian public is receiving drug products that are safe, effective and of high quality. All stakeholders will be invited to participate in a consultative process prior to implementation of this policy.

Scope

This policy applies to all drug products sold in kits for use in humans, with the exception of drugs mentioned or described in Schedule C to the *Act*.

DEFINITIONS

Drug Product:

For the purposes of this policy, a drug product, as identified by a unique DIN, is defined by the brand name, manufacturer's/distributor's name, medicinal ingredient(s)and corresponding strength(s), the pharmaceutical dosage form, and the route of administration.

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Kit:

A kit is a package that contains a collection of two or more drug products having separate DINs, **or** a combination of one or more drug products and non-drug products (e.g. empty, pre-packaged syringes, swabs, tourniquet).

Note: Drug/device combination and drug/delivery system products are not considered to be kits (e.g. pace maker leads containing steroids, metered dose inhalers).

Label:

Includes any legend, word or mark attached to, included in, belonging, or accompanying, any food, drug, cosmetic, device, or package (Section 2 of the *Act*).

Manufacturer/Distributor:

"manufacturer" or "distributor" means a person who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug (A.01.010 of the *Regulations*).

Hereafter, in this policy the "manufacturer" or "distributor" will be referred to as the "manufacturer".

Policy

It is the policy of the Programme that:

1. A separate DIN is required to be issued for each drug product contained in a kit. This DIN may be used for the product to which it is assigned irrespective of whether the drug product is sold as part of the kit or if the drug product is sold separately or as part of another kit.

   In the event that two or more **drug components** are labelled and packaged together by the manufacturer for use together to produce a final **drug product** that is in a form ready to use and with the claim(s) for use in combination, the same DIN will be assigned for the **drug components** (e.g. 'Drug X for Injection' and 'Diluent for Drug X for Injection'). This combination of **drug components** does not in itself constitute a kit as defined above. If the diluent is intended for reconstitution of other drug products, this diluent is considered a **drug product.**

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2. Irrespective of whether a drug product is sold as part of a kit or separately, it must meet the requirements of the *FDA&R*. Drug products and non-drug products contained in kits are also subject to whatever provisions of other *Regulations* that may apply eg. Medical Devices, WHMIS.

3. A manufacturer of a drug, a person authorized by the manufacturer, or in the case of a drug to be imported into Canada, the importer of the drug may make the applications for DINs for the drug products contained in kits. The manufacturer's name (as defined in A.01.010 of the *Regulations*) is to be recorded as the manufacturer/sponsor on the Drug Submission Application Form (HC\SC-XAH400IE(9-93), former designation HPB 3011: see Section 8 Appendix.

4. With respect to labelling requirements, the label on the package containing the kit is considered the outer labelling of the drug product(s). The labelling for drug products sold within a kit must include only those claims and indications of the individual drug products. If claims for any of the drug products are expanded based on concomitant drug administration or use with non-drug components, data must be presented to support those claims for that drug product(s).

5. Any further processing of the drug product, such as sterilization of the kit, also requires submission of supporting data establishing the safety, efficacy and quality of the product.

Responsibilities & Procedures

The regulatory requirements for drug products contained in kits are identical to those for other drug products sold in Canada.

For drug products in kits that require new DINs as a result of this policy, applicants must send the following to the Submission and Information Policy Division, 1620 Scott Street, Unit #14, Address Locator 3000E, OTTAWA, Ontario, K1A 0L2:

1. a completed Drug Submission Application Form HC\SC-XAH400IE(9-93), former designation HPB 3011;

2. labelling material;

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3. a letter of certification stating that all aspects of the application are identical to that of the original submission with the exception of the assignment of the DINs and if applicable the necessary label revisions; and

4. a letter outlining the nature of the request and indicating all DINs that will require withdrawal.

The appendix to this policy is intended to assist applicants with the assignment of DIN's to drug products sold in kits.

These submissions will be processed administratively in an expedited manner, provided the above-mentioned information is submitted.

Effective Date

This policy statement will be implemented immediately for all applications currently in the review process and for new applications related to drug products in kits.

For kits currently sold in Canada, manufacturer of drug products in kits and kit assemblers are required to comply with this policy as of January 1, 1999.

Dann M. Michols
Director General

APPENDIX--GUIDELINES FOR THE ASSIGNMENT OF DINS FOR KITS

The following examples demonstrate the assignment of DINs to drug products sold in kits.

Example 1: Company A applies for a DIN for a drug product to be sold in a kit. Company A purchases this drug product from Company B in order to sell it as part of a kit. Company A is indicated as the manufacturer for this drug product on the Drug Submission Application. The name and address of the manufacturer (Company A) is required on the inner and outer labels of the drug product. This would normally involve relabelling the inner label of the drug product purchased from Company B. There is an exception for the inner label of small containers and for products containing drugs mentioned or described in Schedule D to the *Act* in which cases only the name is required. The name and address of the Canadian importer must appear on the outer and inner labels of the drug product with the exception of the inner label of small containers.

Example 2: Company A applies for a DIN for a drug product to be sold in a kit. Company A purchases this drug product from Company B in order to sell it as part of a kit. Company B is indicated as the manufacturer for this drug product on the Drug Submission Application. The name and address of the manufacturer (Company B) is required on the inner and outer labels of the drug product. There is an exception for the inner label of small containers and for products containing drugs mentioned or described in Schedule D to the *Act* in which cases only the name is required. The name and address of the Canadian importer must appear on the outer and inner labels of the drug product with the exception of the inner label of small containers.

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Labelling

Each drug product contained in a kit must meet all the inner and outer labelling requirements of the *FDA&R*.

For information on labelling requirements refer to the *Food and Drugs Regulations C.01.004, C.01.004.1 and C.01.005, the Drugs Directorate Guideline, Labelling of Drugs for Human Use and the Drugs Directorate Policy Issue, Labelling of Special Containers* dated April 4, 1990. Drug products containing drugs mentioned or described in Schedule D to the *Act* should be labelled in accordance with the *Food and Drugs Regulations C.01.004.1, C.01.005, C.04.019 and C.04.020.*

The label on the package containing the kit is considered the outer labelling of the drug product(s). The outer label should include the following: the product name of all drug products within the kit; the proper name of all drug products within the kit; the manufacturer of each drug product; associated DIN for each drug product; adequate directions for use; the Canadian importer; the lot number of each drug product; and an expiry date for the kit that is based on the earliest expiry date of the drug products within the kit.