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.
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

Attachment
Mr. Charles Low
President
Canadian Cosmetic, Toiletry and Fragrance Association
5090 Explorer Drive
Suite 510
MISSISSAUGA, Ontario
L4W 4T9

Ms Brenda Drinkwalter
President
Canadian Drug Manufacturers Association
4120 Yonge Street
Suite 606
NORTH YORK, Ontario
M2P 2B8

Mr. Serge Lavoie
Executive Director
Canadian Health Food Association
550 Alden Road, Suite 205
MARKHAM, Ontario
L3R 6A8

Mr. Mario Ménard
Director General
Canadian Homeopathic Pharmaceutical Association
43 Balsam Street
BAIE D'URFÉ, Québec
H9X 3K6

Mr. Stephen Chambers
Chair, Antimicrobial Chemicals Division
Canadian Manufacturers of Chemical Specialties Association
56 Sparks Street
Suite 500
OTTAWA, Ontario
K1P 5A9

Mr. Ross Creber
President
Direct Sellers Association
100 West Beaver Creek Road, #3
RICHMOND HILL, Ontario
L4B 1H4

Ms Joyce Groote
President
Industrial Biotechnology Association of Canada
130 Albert Street
Suite 420
OTTAWA, Ontario
K1P 5G4

.../2
Mr. Dennis Bryant  
President  
Medical Devices Canada  
401 The West Mall, Suite 510  
ETOBICOKE, Ontario  
M9C 5J5

Mr. David Skinner  
President  
Nonprescription Drug Manufacturers  
Association of Canada  
1111 Prince of Wales Drives  
Suite 406  
OTTAWA, Ontario  
K2C 3T2

Mr. Henri Vienneau  
Co-Chairman  
Nuclear Medicine Alliance  
President-General Manager  
Mallinckrodt Medical Inc.  
7500 route Trans-Canadienne  
POINTE-CLAIRE, Quebec  
H9R 5H8

The Honourable Judy Erola, P.C.  
President  
Pharmaceutical Manufacturers  
Association of Canada  
302-1111 Prince of Wales Drive  
OTTAWA, Ontario  
K2C 3T2

Mr. John H. Stewart  
Executive Vice-President  
and General Manager  
Purdue Frederick  
575 Granite Court  
PICKERING, Ontario  
L1W 3W8

Mrs. Jean Szkotnicki  
President  
Canadian Animal Health Institute  
27 Cork Street West  
GUELPH, Ontario  
N1H 2W9
Dr. Daniel B. Vickery  
Chairperson  
Canadian Association of Pharmaceutical Regulatory Affairs  
c/o Parke-Davis  
2200 Eglinton Avenue East  
SCARBOROUGH, Ontario  
M1L 2N3

Mr. Michel Nadeau  
Vice President, Public Affairs  
and Member Services  
Canadian Council of Grocery Distributors  
300 Léo-Pariseau Street, Suite 1100  
P.O. Box 1082, Place du Parc  
MONTREAL, Quebec  
H2W 2P4

Ms Diane Gosling  
Executive Director  
Canadian Sanitation Supply Association  
300 Mill Road, #G-10  
ETOBICOKE, Ontario  
M9C 4W7

Ms Elizabeth A. Rafuse  
President  
Canadian Society of Regulatory Affairs  
5691 Main Street  
STOUFFVILLE, Ontario  
L4A 0H5

Mrs. Theresa Firestone  
President & CEO  
Canadian Wholesale Drug Association  
5255 Yonge Street, Suite 505  
NORTH YORK, Ontario  
M2N 6P4

Mr. Raymond Reilly  
President  
Canadian Association of Radiopharmaceutical Scientists  
Radiopharmacy, Division of Nuclear Medicine  
Toronto General Hospital  
200 Elizabeth Street  
TORONTO, Ontario  
M5G 2C4
Mr. Gerald H. Dafoe  
Executive Director  
Canadian Public Health Association  
1565 Carling, Suite 400  
OTTAWA, Ontario  
K1Z 8R1

Mr. Bill Leslie  
Executive Director  
Canadian Society of Hospital Pharmacists  
Suite 350, 1145 Hunt Club Road  
OTTAWA, Ontario  
K1V 0Y3

Ms Rosalie Daly  
Executive Director  
Consumers’ Association of Canada  
267 O’Connor Street  
OTTAWA, Ontario  
K2P 1V3

Ms Linda Nagel  
President and CEO  
Canadian Advertising Foundation  
350 Bloor Street East  
Suite 402  
TORONTO, Ontario  
M4W 1H5

Dr. Art Olson  
President  
Canadian Food Inspection Agency  
59 Camelot Court  
NEPEAN, Ontario  
K1A 0Y9

Barbara A. Wells, B.Sc, Phm.  
Executive Director  
National Association of Pharmacy Regulatory Authorities  
#305-116 Albert Street  
OTTAWA, Ontario  
K1P 5G3

Mr. Pierre Paul Demers  
Acting Director  
National Council on Bioethics in Human Research  
774 Echo Drive  
OTTAWA, Ontario  
K1S 5N8
Mr. Wayne Critchley  
Executive Director  
Patented Medicine Prices Review Board  
Box L40, Standard Life Centre  
333 Laurier Avenue West  
OTTAWA, Ontario  
K1P 1C1  

Mr. Mark McElwain  
Commissioner  
Pharmaceutical Advertising Advisory Board  
375 Kingston Road  
Suite 200  
PICKERING, Ontario  
L1V 1A3  

Mr. Chris Dubé  
Association of Medical Manufacturers (AOMM)  
c/o Cardiomed Supplies Inc.  
P.O. Box 385  
GORMLEY, Ontario  
L0H 1G0  

Mr. Andy Frank  
President  
Manitoba Health Organization  
c/o VistaMed  
633 Wellington Cres.  
WINNIPEG, Manitoba  
R3M 0A8  

Mr. David Hood  
President  
Calgary Association for Medical Products  
Box 22207  
CALGARY, Alberta  
T4P 4J5  

Mr. John Rikley  
President  
Carol Heatherington  
Healthcare Opportunities Metro Edmonton  
9797 Jasper Avenue  
EDMONTON, Alberta  
T5J 1N9
Mr. Ron Evans  
Medical Device Industry  
Association of British Columbia  
c/o Jack Bell Research Centre  
2660 Oak Street  
VANCOUVER, B.C.  
V6H 3Z6

Mr. Andre Gour  
Sector Manager  
Medical Devices Health Products  
Exports Association  
Medical and Biopharmaceuticals  
British Columbia Trade and Investment Office  
Suite 730, 999 Canada Place  
VANCOUVER, B.C.  
V6C 3E1

Ms. Eva Young  
President  
Dental Industry Association of Canada  
c/o Sci-Can  
260 Yorkland Boulevard  
TORONTO, Ontario  
M2J 1R7
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.
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.
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;
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.