

Tunney's Pasture/Pré Tunney  
OTTAWA, Ontario  
K1A 0L2

May 18, 1999

Le 18 mai 1999

**Publication of Schedule of Amendments**

**Publication d'une liste de modifications**

Please be advised that the following Schedule appears in the *Canada Gazette*, Part I of:

Veillez prendre note que l'annexe qui suit apparaît dans la *Gazette du Canada*, Partie I du:

**DATE**

May 22, 1999

**DATE**

22 mai 1999

**SCHEDULE**

*Food and Drug Regulations* - Amendment  
Schedule No. 743  
Non-medicinal Ingredient Labelling

**ANNEXE**

Règlement sur les aliments et drogues -  
Modification  
Annexe No. 743  
Déclaration des ingrédients nonmédicamenteux  
sur les étiquettes

Interested persons may make representations concerning the proposed amendments to the Responsible Officer, Policy Division, Bureau of Policy and Coordination, 1600 Scott St., 2nd. Floor, Holland Cross, Tower B, Address Locator 3102C5, Ottawa, Ontario, K1A 1B6, within 30 days of the date of publication of this Schedule. All such representations should cite *Canada Gazette* Part I, the date of publication of the Schedule and Schedule No. 743.

Les personnes intéressées peuvent présenter à l'agent responsable, Division de la politique, Bureau des politiques et de la coordination, 1600 Scott St., 2ième étage, Tour B, Holland Cross, Indice de l'adresse 3102C5, Ottawa, Ontario, K1A 1B6 leurs observations sur les modifications proposées, dans les 30 jours suivant la publication de l'annexe. Elles sont priées d'y citer la *Gazette du Canada*, Partie I, la date de publication de l'annexe et l'annexe No. 743.

Karolyn Lui  
Regulatory Officer  
Policy Division / Division de la politique

Attachments

Pièces jointes

## REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the regulation)

### ***Background and Description***

This is the third publication of the proposed amendments to the *Food and Drug Regulations* to require pharmaceutical distributors to declare all non-medicinal ingredients (NMIs) on the labels of all drug products for human use, except those drugs which are:

- i) required to be sold by prescription,
- ii) available without a prescription and not recommended for self-administrations, and
- iii) for use as disinfectants on inanimate objects.

Due to the extensive response received in previous publications in the *Canada Gazette*, Part I (On December 2, 1989 and on February 5, 1994), the original regulatory proposal has been revised.

It has been established that there is direct association between NMIs in drug products and the adverse effects produced in individuals with particular sensitivities or allergies. The declaration of such ingredients on product labels will enable those individuals to make an informed choice and to avoid agents known to cause adverse reactions. In addition it would assist in the identification of causative agents when reactions do occur.

The proposed implementation date of these regulations is January 1, 2000.

### ***Alternatives Considered***

Maintaining the status quo, which requires only the label declaration of medicinal ingredients, does not meet the information needs of those individuals who are allergic or sensitive to particular NMIs.

In early 1985, voluntary guidelines for the disclosure of selected NMIs were adopted by the Nonprescription Drug Manufacturers Association of Canada (NDMAC). This information was to be made available on the labels of non-prescription drug products. NMI Information for prescription drug products was to be made available for inclusion in the *Compendium of Pharmaceuticals and Specialties*, a private publication available to health professionals. However, the lack of universal acceptance of the voluntary guidelines, their inconsistent application and selective disclosure have not fulfilled the needs of consumers.

Partial label disclosure of only those ingredients known to cause reactions has not proven to be a reasonable alternative. Not all potential sensitizing agents are identified. Full label disclosure will eliminate the difficulties associated with the identification of ingredients which are suspected or most likely to be the cause of adverse effects, or those which individual consumers may wish to avoid.

### ***Benefits and Costs***

This proposed amendment will impact on the following sectors:

- ! Public

Consumers will be provided with ready access to meaningful information on the NMI content of over-the-counter (OTC) drugs to take home for future reference. The listing of NMIs will allow consumers to make an informed choice when purchasing nonprescription drugs. It is anticipated that mandatory NMI labelling should lead to fewer repeat adverse reactions.

#### **! Pharmaceutical Industry**

The major costs associated with these regulations will be incurred by the pharmaceutical industry. The cost will, however, be minimized by deferring the implementation of the regulatory amendments until January 1, 2000. This transition period will allow the depletion of existing label supplies and allow packagers to introduce the changes within the normal label life cycle hence reducing cost. Many pharmaceutical companies have already voluntarily complied with this proposal and hence will not have any added costs.

There will be a small increase in paper burden to industry resulting from the requirement to include the non-medicinal ingredient information when applying for a Drug Identification Number (DIN). For distributors of products already on the market, an updating of previously submitted information will be required.

Increased consumer awareness may cause fabricators to amend product formulations to remove ingredients known to be sensitizers or ingredients which are otherwise unacceptable. This will result in the availability of products which are less likely to produce undesirable effects.

Qualitative and quantitative declaration at the time of application for a DIN will not increase the existing paper burden of the distributor.

#### **! Provincial Health Care System**

There may be a lower cost for physician and healthcare systems as a result of reduced adverse drug reaction incidents.

#### **! Federal Government**

There would be minor increases in government costs to maintain current non-medicinal ingredient information and to ensure compliance.

The submission of NMI information by distributors may be used by government in correlation with the drug adverse reaction reporting system, to assist in determining the possible association between such reactions and these ingredients, in addition to the medicinal ingredients.

### ***Consultation***

These amendments have been the subject of extensive informal discussions and formal consultations

with interested parties, as follows:

- Information Letter No. 733, published on January 15, 1988 was distributed to all drug manufacturers, health professional associations and public advocacy groups;
- recommendations were tabled in the fourth report to the House of Commons on July 14, 1988;
- the previous publication of regulatory amendments in *Canada Gazette*, Part I on December 2, 1989;
- a meeting with representatives of the pharmaceutical industry, consumer organizations and health professional organizations on September 28, 1990, to present a revised regulatory proposal and solicit comments;
- extensive correspondence with all stakeholders, including pharmaceutical manufacturing organizations, individual pharmaceutical manufacturers, pharmaceutical licensing bodies, individual pharmacists, organizations of the profession of pharmacy, provincial ministries of health, consumer advocacy groups, organizations of the profession of medicine and individual physicians on the status and revisions to the NMI initiative.
- questions included in a survey of physicians and pharmacists conducted for the Health Protection Branch in September 1992 to determine the usefulness of NMI information in their practices.
- the previous publication of regulatory amendments in *Canada Gazette*, Part I on February 5, 1994.

As a result of these consultations, the regulatory proposal has received support from the medical profession, consumer groups and health organizations. The pharmaceutical manufacturing sector has generally agreed with the principle of full mandatory disclosure of NMIs, and is participating in a working group on the nomenclature of these ingredients.

### **Proposed Changes from Previous Publications**

As a result of the Programme's continued effort to develop an acceptable regulatory framework, the following changes are now proposed:

1. Drugs Exempted from Mandatory NMI labelling:
  - a. Prescription drugs
  - b. Drugs available without a prescription but not recommended for self-administration.
  - c. Disinfectants or hard surface cleaners for use on inanimate surfaces or objects, for the disease prevention of medical devices, health care facilities or premises in which food is manufactured, prepared or kept.
  - d. Veterinary Drugs

The primary objection to label disclosure was for prescription drug products, on the basis that the proposed regulations were impractical. Label information will not reach the consumer. Alternatives, such as making this information accessible in databases and reference publications are also impractical as the information would not be available and accurate at the time of purchase of the drug product.

Drugs available without a prescription but not recommended for self-administration are products which are generally considered to be “prescribed” and are not available for self-selection or self-administration without the intervention of a health professional.

Disinfectants and hard surface cleaners for use on inanimate surfaces or objects have been exempted from this proposal. This issue of labelling for these products will be examined and addressed under the disinfectant framework.

There does not appear to be evidence of serious adverse reactions to oral or topical veterinary products in animals.

However, the identity of all non-medicinal ingredients in these exempted drugs will be available, to any person, from the distributor upon request.

## 2. Definitions

The definition of “**flavour**” has been changed to:

any ingredient or combination of ingredients in a drug used solely to impart only a taste to the drug but does not include an ingredient or combination of ingredients that imparts only a sweet taste to the drug.

Similarly, “**fragrance**” means:

any ingredient or combination of ingredients in a drug used solely to impart only a smell to the drug.

This revision requires the identity of neutralizing and masking agents to be listed, in alphabetical or descending order with other NMIs. Previous regulatory amendments proposed that these agents be permitted to be declared as “fragrance” or “flavour” even on unscented drug products. The revised proposal will eliminate confusion when declaring the existence of a fragrance added in an unscented product. In addition, the identity of the neutralizing or masking agent will provide additional NMI information to consumers.

## 3. Order of Declaration

This proposal provides additional flexibility in the order of declaration. One of the major concerns expressed by stakeholders is the change to alphabetical ordering of NMIs, rather than descending order, as initially proposed. Some distributors have already voluntarily labelled their OTC drugs using descending order of NMIs. To relabel would mean an additional unnecessary cost and inconvenience to those who voluntarily complied, without any additional value in information. The amended proposal will allow a choice in the way NMIs are listed but will mandate the use of a header on the label indicating the type of listing used.

#### 4. Designation on NMIs on labels

This regulatory amendment still allows for the distributor's own wording to designate NMIs but the heading must clearly distinguish the NMIs from the medicinal ingredients.

The phrase "may contain" will still be acceptable, where the NMI composition of the drug varies from one lot to another, without requiring relabelling of the product.

The labelling would be required to advise consumers when NMI formulation changes are made. The labelling may contain the NMI listing for both a new and old formulation of a product. When this label is used, the label on the package must indicate which formulation applies to that product in that package.

#### 5. Location of NMI disclosure on Labelling

The listing of the NMIs will appear on the label on or affixed to the outside of a package of a drug.

#### 6. Small Containers

Subsection C.01.004(3) of the Food and Drug Regulations proposes declaring labelling information on an outer label where the inner label is too small to accommodate it.

This proposal includes an additional provision for small containers. In the case of a drug displayed for sale in trays or display stands, the use of leaflets or padded sheets may be used to identify NMIs provided that the following requirements are met:

- The labelling information holder is attached to the display unit and is easily accessible to the consumer.
- All NMI labelling material used with any one display unit is identical and declares the NMIs for all products sold in that display unit.
- Sufficient copies of the labelling material will be provided to accompany each purchase.
- All NMI labelling information accompanying refills are attached to or packed with that specific refill in a container that does not contain other drug products.
- Instructions to the retailer will be accompanied with the shipment so that compliance at the retail level can be ensured.

#### 7. Drug Submission Requirement

For applications for which a drug identification number (DIN) is made before January 1, 2000, every distributor of a drug will be required, at the time of annual notification (before October 1, 2000) to supply to the Director, the proper name or common name and the quantity of each non-medicinal

ingredient in the drug.

***Compliance and Enforcement***

This amendment does not alter existing compliance mechanisms under the provisions of the *Food and Drug Act and Regulations* enforced by Therapeutic Product Programme Inspectors.

***Contact***

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Notice is hereby given that the Governor in Council, pursuant to section 30\* of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (743 — Non-medicinal Ingredients)*.

Interested persons may make representations with respect to the proposed Regulations within 30 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Karolyn Lui, Therapeutic Products Programme, Department of Health, Address Locator No. 3102C5, 1600 Scott Street, Holland Cross, Tower B, 2<sup>nd</sup> Floor, Pasture, Ottawa, Ontario K1A 1B6.

The representations should stipulate those parts of the representations that should not be disclosed pursuant to the *Access to Information Act* and, in particular, pursuant to sections 19 and 20 of that Act, the reason why those parts should not be disclosed and the period during which they should remain undisclosed. The representations should also stipulate those parts of the representations for which there is consent to disclosure pursuant to the *Access to Information Act*.

Ottawa,

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Marc O'Sullivan  
Assistant Clerk of the Privy Council

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\* S.C. 1994, c. 47, s. 117

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (743 — NON-MEDICINAL INGREDIENTS)

AMENDMENTS

**1. Subsection C.01.001(1) of the *Food and Drug Regulations*\* is amended by adding the following in alphabetical order:**

"fabricator" means a person who prepares and preserves a drug for the purposes of sale;  
(*manufacturier*)

"flavour" means any non-medicinal ingredient or combination of non-medicinal ingredients in a drug used solely to impart a taste to the drug, but does not include an ingredient or combination of ingredients that imparts only a sweet taste to the drug; (*aromatisant*)

"fragrance" means any non-medicinal ingredient or combination of non-medicinal ingredients in a drug used solely to impart a smell to the drug; (*parfum*)

"medicinal ingredient" means any substance that is present in a drug and in respect of which therapeutic activity is claimed; (*ingrédient médicinal*)

"non-medicinal ingredient" means any substance, other than a medicinal ingredient, used in the fabrication of a drug and intended to be present in the dosage form in which the drug is to be sold; (*ingrédient non médicinal*)

**2. (1) Section C.01.004 of the Regulations is amended by adding the following after subsection (1):**

(1.1) In addition to the requirements of subsection (1) and subject to paragraph (1.3)(e), where a drug is intended for human use

(a) the outer label of the drug shall list, by their proper names or by their common names, all non-medicinal ingredients in the drug; or

(b) if the outer label does not have sufficient space for a list of non-medicinal ingredients and the drug is displayed for sale in a display unit, a list of all non-medicinal ingredients in the drug, designated by their proper names or by their common names, shall appear on labelling in the form of tear-off sheets or leaflets and the following requirements shall be met:

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\* C.R.C., c. 870

(i) the holder of the tear-off sheets or leaflets bearing the list of non-medicinal ingredients is attached to the display unit and is located in such a manner that the tear-off sheets or leaflets are easily accessible to a purchaser facing the display unit under customary conditions of retail sale,

(ii) the tear-off sheets or leaflets used in conjunction with the display unit shall be identical and shall list the non-medicinal ingredients of all products offered for sale on the display unit,

(iii) sufficient copies of the tear-off sheets or leaflets listing the non-medicinal ingredients are provided by the manufacturer to the retailer with each shipment of a drug so that the purchaser may obtain a copy of the list with each purchase,

(iv) copies of the list of non-medicinal ingredients are provided by the manufacturer with refills of the drug or are packed by the manufacturer with refills of the drug in a container that does not contain any other drugs, and

(v) the labelling for the display unit is accompanied by instructions from the manufacturer to the retailer which, when followed, will result in compliance with this paragraph.

(1.2) Subsection (1.1) does not apply to

(a) a drug required to be sold pursuant to a prescription, or a drug available without a prescription that is not recommended for self-administration, provided that the identity of all non-medicinal ingredients in the drug, by their proper or common names, is available from the distributor to any person upon request; or

(b) a drug that is represented as being solely for use as a disinfectant on inanimate surfaces or objects, for the prevention of disease on premises in which food is manufactured, prepared or kept.

(1.3) The list of non-medicinal ingredients referred to in subsection (1.1)

(a) shall, subject to paragraphs (e) and (f), be arranged in alphabetical order by their proper names or their common names or in descending order of their proportion of the drug;

(b) shall be preceded by words that

(i) clearly distinguish the non-medicinal ingredients from the medicinal ingredients, and

(ii) indicate the order of listing;

(c) shall, where any formulation change is made, clearly advise the purchaser that the formulation has been changed, so as to enable the purchaser to identify the changes in the non-medicinal ingredients;

(d) shall, where any formulation change is made and the labelling containing the list of non-medicinal ingredients is thereby required to be used in conjunction with products of both the old and new formulations, list separately the non-medicinal ingredients of both the old and new formulations

so that the purchaser will not be misled and will be able to identify the list of non-medicinal ingredients applicable to each package, or clearly advise the purchaser that the formulation has been changed and that either list may be applicable;

(e) may, in the case of a flavour or fragrance, disclose only the existence of the flavour or fragrance in the drug, where

(i) the fabricator or the distributor of the drug, a person authorized by the fabricator or the distributor or, if the drug is imported into Canada, the importer of the drug maintains, in Canada, a record of the following information:

(A) the proper name of the flavour or fragrance,

(B) the common name or brand name of the flavour or fragrance,

(C) the quantity of the flavour or fragrance in the drug, and

(D) the name of the supplier of the flavour or fragrance to the fabricator, distributor, authorized person or importer, or to the fabricator or distributor of any ingredient in the drug, as the case may be, and

(ii) the supplier referred to in clause (i)(D) or a person authorized by the supplier maintains, in Canada, a record of the following information:

(A) the proper name of the flavour or fragrance,

(B) the common name or brand name of the flavour or fragrance,

(C) the quantity of the components of the flavour or fragrance;

(f) may, where the composition of the drug varies from one lot to another, include a reference, distinguished by the use of the words "may contain", to any other non-medicinal ingredient that may, as an alternative to any non-medicinal ingredient referred to in the list, be present in the drug; and

g) shall, where ingredients, trace components of ingredients or trace amounts of processing aids, which are not intended to be present in the dosage form in which the drug is to be sold, may be derived from a known allergen, including peanuts, nuts, molluscs, crustaceans, fish or eggs, indicate the source of the ingredients or include a statement that the drug "may contain" peanuts, nuts, molluscs, crustaceans, fish, eggs or any other allergen, as the case may be.

**(2) The portion of subsection C.01.004(2)\*\* of the Regulations before paragraph (a) is replaced by the following:**

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\*\* SOR/80-543

(2) In addition to the requirements of subsection (1) and, where applicable, subsections (1.1) and (1.3), the outer label of a drug shall show

**3. Paragraph C.01.014.1(2)(h)<sup>\*\*\*</sup> of the Regulations is replaced by the following:**

(h) the proper name or common name of each non-medicinal ingredient in the drug;

(h.1) the quantity of each non-medicinal ingredient in the drug;

**4. Section C.01.014.4 of the Regulations is renumbered as subsection C.01.014.4(1) and is amended by adding the following:**

(2) Where an application for a drug identification number was made before January 1, 2000, every distributor of the drug shall, at the time of annual notification under section C.01.014.5 and before October 1, 2000, furnish to the Director the proper name or common name and the quantity of each non-medicinal ingredient in the drug.

(3) Paragraph (1)(b) applies, with such modifications as the circumstances require, in respect of information given pursuant to subsection (2).

**5. Paragraph C.01.014.6(2)(a)<sup>3</sup> of the Regulations is replaced by the following:**

(a) there has been a failure to comply with the requirements of subsection C.01.014.4(2) or section C.01.014.5 in respect of the drug; or

**6. The definition "fabricate" in subsection C.01A.001(1) of the Regulations is deleted.**

**7. (1) The portion of section C.04.019 of the Regulations before paragraph (a) is replaced by the following:**

**C.04.019.** Subject to subparagraph (b)(vi), the provisions of section C.01.004 do not apply to a drug as defined in this Division, but every package of such drug shall carry

**(2) Paragraph C.04.019(b) of the Regulations is amended by striking out the word "and" at the end of subparagraph (iv), by adding the word "and" at the end of subparagraph (v) and by adding the following after subparagraph (v):**

(vi) a list of the non-medicinal ingredients in the drug which shall

(A) subject to paragraph C.01.004(1.3)(e), show the non-medicinal ingredients by their proper names or by their common names, and

(B) comply with paragraphs C.01.004(1.3)(a) to (d), (f) and (g).

COMING INTO FORCE

**8. These Regulations come into force two years after their registration.**