

Voluntary Labelling Program for Significant Changes to Products

Introduction

Manufacturers of consumer health products make changes in their products to improve safety or increase effectiveness, either as a result of the development and recognition of new scientific data or by providing more detailed labelling information. Additionally, consumer health product companies introduce, under an existing brand name, new products which may contain different single ingredients or new combinations of ingredients, in order to provide a broader range of available self-care options.

A voluntary program has been adopted by members of Consumer Health Products Canada to aid in alerting the public to significant changes in consumer health products. Industry will continue to ensure the development of outer labels that will alert Canadians to significant new information. Members of Consumer Health Products Canada will strive to implement the program as they make significant changes in their currently marketed consumer health products or introduce new products under an existing brand name.

Significant Changes to a Currently Marketed Consumer Health Product

Manufacturers of consumer health products will use the label to alert the public when significant changes are made to currently marketed products. "Significant Changes" include:

- Expansion or limitation of indications (claims);
- Material modification of dosage level;
- Change in active ingredients or in directions for use;
- New warnings or new contraindications; or
- Any other significant new information.

This program can be met by using phrases such as the following (or words of similar meaning), with the goal of being as specific as possible in relation to the significant change that is being undertaken:

- "See new directions"
- "See new label directions"
- "New information: Read entire label"
- "See label for new ingredients"
- "See new warnings"
- "Read label for current directions and warnings"
- "See new uses"
- "See new use"
- "See new dosage"



To assure that the public is alerted to these changes, the changes should be readily apparent. Means to accomplish this could include the following:

1. being carried in type size and style which is conspicuous;
2. being set off by a distinctive colour or type of background from other information; and
3. being carried for at least six months after such a change is made.

New Products Introduced Under Existing Brand Names

Manufacturers of consumer health products will use the label to alert the public to all new products introduced under an existing brand name. The outer label should explain the unique/new product feature(s). The following are some examples of how manufacturers can alert the public.

If the brand name line extension is the addition of another ingredient(s), then phrases such as the following (or similar applicable phrases) could be used to meet this program:

- "Added new ingredient"
- "Added new ingredients"

If the brand name line extension is a change in the ingredient, then the program could be met with the following phrase (or phrase of similar meaning):

- "Contains no (insert type of ingredient that is in the brand name product, such as "antihistamine") - i.e., "Contains no antihistamine"

or

- "(insert name of new ingredient, such as "decongestant"), no (insert name of ingredient that is in the brand name product, such as "antihistamine")"- i.e. "decongestant, no antihistamine"

If the brand name line extension is an extension of a line of products into new pharmacologic categories (e.g., an antacid product now expanded for relief of constipation), then this program could be met by the use of the following phrases (or phrases of similar meaning):

- "For (insert new indication category, such as "constipation")" - i.e., "For constipation"

If the brand name line extension is a new dosage or dosage form, then the use of the following phrases (or phrases of similar meaning) would meet this program:

- "New dosage"
- "New timed release formula"
- "New dosage form"

The above mentioned examples are not meant to cover all possible situations, but rather to help add specificity to the words and phrases used in the label to describe the new changes.



Communicating With Health Professionals

In order to help ensure that the health care profession are alerted to product changes, companies should make appropriate notification to the profession (e.g., Dear Doctor Letter, Dear Health Professional Letter, notices to editors of pharmacy and journals, appropriate compendia, etc.), according to the nature of the product(s) and the change(s) being made.

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