LAXATIVES-LABELLING STANDARD

1. CLASSIFICATION

I Bulk-forming
II Carbon dioxide-releasing
III Hyperosmotic
IV Kit Bowel Cleansing System
V Lactulose
VI Lubricant
VII Saline
VIII Stimulant
IX Stool Softeners

N.B. consult individual labelling standards

NOTE: In the case of applications for drugs which fit the criteria of this labelling standard, it is not necessary to conduct an assessment to determine if bioequivalence, pharmacodynamic/clinical studies or pharmaceutical equivalence data must be submitted.

2. INDICATIONS FOR ALL CLASSES

(i) Acceptable Claims:

- promotes bowel movement by increasing bulk volume and water content (bulk-forming)
- gentle relief of occasional constipation (bulk-forming)
- to relieve irregularity
- relief of occasional constipation
- promotes evacuation of the lower bowel (carbon dioxide)
- acts on the intestine to promote a bowel movement (lactulose)
- increases water in the intestine, thereby promoting bowel movement (saline)
- promotes bowel movement by direct actions on the intestine (stimulant)
- promotes evacuation of the lower bowel (lubricant/emollient)
- softens the stool (lubricant/emollient)

(ii) Non-Acceptable Claims:

- regular use
- treatment for obesity
- laxative is "natural" because of it's source - this implies that the product or ingredient is a "natural way" to induce a bowel movement
- relieves indigestion, excessive belching, after-meal discomfort, headaches or biliousness

created:1985
revised:94-09-01

3. WARNINGS - CAUTIONARY STATEMENTS

1. Do not use in the presence of abdominal pain, nausea, fever or vomiting (this refers to signs of appendicitis or inflamed bowel) .

2.
a) that overuse or extended use may cause dependence for bowel function (NB. not required for bulk forming lax.)
b) not to take any type of laxative for more than one (1) week, unless your physician has ordered a special schedule for you
c) that a laxative should not be taken within two (2) hours of another medicine because the desired effect of the other medicine may be reduced

3. Caution for Psyllium powder products:

"This product may cause an allergic reaction in people sensitive to inhaled or ingested psyllium powder. AVOID INHALATION."

4. Cautions for glycerin suppositories:
Only 1. and 2. (b).

5. Cautions for sodium phosphate rectal enema, bisacodyl suppositories:
Only 1., 2. (a), and 2. (b).

6. Cautions for mineral oil enemas
Only 1., 2. (b).

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

4. REFERENCES

US FDA OTC Review Panel Tentative Final Monograph: January 15, 1985
Canadian Self-Medication, Second Edition, 1984
Handbook of Nonprescription Drugs, Seventh Edition, 1982
United States Pharmacopeia Dispensing Information, 1985
Martindale, Twenty-eighth Edition

Product Regulation Division
Bureau of Nonprescription Drugs
created:1985
revised:94-09-01