LABELLING STANDARD

INTESTINAL FLORA MODIFIERS

I) Description:

This labelling standard applies to products in oral dosage form recommended solely for restoring, normalizing or stabilising the intestinal flora (C.01.004). The bacteria (medicinal ingredients) are restricted to those specified in this standard. They must be identified on product labelling by the names given in this standard.

Special Note:

i) Products with any indication beyond those given in IV b) i) are subject to the licensing requirements of Division 4 of the Food and Drug Regulations and are, therefore, excluded from this Labelling Standard (Such products will be referred to the Bureau of Biologics).

ii) All combinations of non-microbial medicinal ingredients with microbial ingredients will be excluded from this Labelling Standard.

II) Pharmaceutical Quality:

a) All ingredient (microbial and nonmedicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B to the Food and Drugs Act, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product’s identity, potency (the number of viable microorganisms per unit of dosage), purity and quality.

b) As a minimum, the manufacturer must have data available to support the identity, potency*, purity and quality of the product as follows:

* Note that the potency must reflect the number of viable organisms to which a consumer will be exposed upon consumption within the established timeframe to expiry.

i) Information on the source and history of the microorganism, confirmation of identity of the species, strain, etc.

ii) Details on the fermentation process such as information on the culture medium(s), pH, temperature, isolation techniques,

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etc..

iii) Appropriate finished product specifications such as information on the purity, safety of the product (including contaminants), potency, etc. The specifications for all dosage forms should include a description of the dosage form including organoleptic properties as well as physico-chemical testing e.g., pH, specific gravity, viscosity, appropriate to the dosage form.

III) **Ingredients:**

a) **Acceptable bacterial strains:**

   i) *Lactobacillus acidophilus*
   
   ii) *Lactobacillus bulgaricus*
   
   iii) *Lactobacillus casei*
   
   iv) *Lactobacillus helveticus*
   
   v) *Bifidobacterium bifidum*
   
   vi) *Bifidobacterium longum*

b) **Combinations of Medicinal Ingredients:**

   i) Combination of only those microbial ingredient(s) listed in III a) is permitted.

IV) **Labelling:**

a) 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 must also be met.

b) **Directions for Use:**

   i) **Indications**

      1. The primary indication shall be

         For restoring and/or normalising and/or stabilising the intestinal flora

   ii) **Dosage Directions:**

      **Single and Combination Ingredients products:**
1) Adults and children over 12:
   "X" capsules to provide a single dose of: 2 billion
   "Y" capsules to provide a maximum daily dose of: 8
   billion

2) For those unable to take capsules, the contents of the
   capsules may be mixed with cold food or liquid

   iii) **Warnings:**

   1) Do not use for more than 5 days except on the advice of
      a doctor;

   2) Do not use in the presence of abdominal pain, nausea,
      fever, vomiting, or bloody diarrhea;

   3) If symptoms worsen, consult a doctor

V) **REFERENCES:**


2. **Drugdex, Drug Evaluation Monographs**: Lactobacillus

3. Brennan et al. (1993) Prevalence of Viable Lactobacillus acidophilus in
   887-892


5. **Compendium of Nonprescription Products**, Canadian Pharmaceutical