LABELLING STANDARD

NON-CLASSICAL ANTIHISTAMINES

I) Description:

This labelling standard applies to products containing histamine H_1-receptor antagonist ingredients for OTC oral use as antihistamines.

II) Medicinal Ingredients:

1. Loratadine
2. Cetirizine

All subject to the requirements of Division 8, Part C of the *Food and Drug Regulations*.

III) Adequate Directions for Use:

1. **Indications:**

   a) For the relief of hayfever and allergy symptoms:

      i) sneezing
      ii) runny nose
      iii) itchy, watery eyes
      iv) allergic skin conditions such as hives

IV) Miscellaneous Label Statement:

1) Product Monograph available to physicians and pharmacists on request

2) **Other claims:**

   a) Non-drowsy/Non-sedating:

      See the Drugs Directorate Policy entitled "Absence of Side Effect Claims for Nonprescription Drugs".

V) References:

1. **Compendium of Pharmaceutical Specialties**, Twenty-sixth edition, 1991.

2. **Drug Evaluations Subscription**, American Medical Association, 1990.

3. **United States Pharmacopoeia Dispensing Information**, USPDI 1992, Drug Information for the Health Care Professional.

4. **Martindale, The Extra Pharmacopoeia**, 29th Edition, 1990, Philadelphia College of Pharmaceutical Sciences.

5. **Canadian Drug Identification Code**, Eighteenth Edition, 1992, Health and Welfare Canada.

LORATADINE

I) Description:

This labelling standard applies to products that contains loratadine as a single medicinal ingredient in the pharmaceutical form of a tablet **or syrup.**

II) Medicinal Ingredients and Concentrations:

1. Loratadine 10 mg per tablet

2. Loratadine syrup 1 mg per ml

III) Adequate Directions for Use:

1. **Indications:**

   a) As for all ingredients (see page 1).

2. **Dosage Directions:**

   a) Tablets:

      Adults and children 12 years of age and over: One tablet, (10 mg) once per day.

   b) **Syrup:**

      i) Adults and children 10 years of age and over (body weight greater than 30 kg): 10 ml (two teaspoonfuls) of syrup once per day

      ii) Children 2 to 9 years of age (body weight less than or equal to 30 kg): 5 ml (one teaspoonful) of syrup once per day

      iii) Not recommended for children under two years of age

      iv) Use by children between the ages of 2 and 12 for longer than 14 days, use only as directed by a doctor

3. **Warnings:**

1. "**DO NOT EXCEED RECOMMENDED DOSAGE**" should immediately follow the dosage directions.

2. Prolonged usage should be only on the advice and direction of a physician.

3. Pregnant or nursing mothers should not use this product, unless advised by a physician.

CETIRIZINE

I) Description:

This labelling standard applies to products that contains Cetirizine as a single medicinal ingredient in the pharmaceutical form of a tablet.

II) Medicinal Ingredients and Concentrations:

1. Cetirizine 5 and 10 mg per tablet

III) Adequate Directions for Use:

1. **Indications:**

   a) As for all ingredients (see page 1).

2. **Dosage Directions:**

   a) Adults and children 12 years of age and over: one tablet, (5 or 10 mg) once per day. Elderly patients take one 5 mg tablet per day or consult a physician

3. **Warnings:**

   1. "**DO NOT EXCEED RECOMMENDED DOSAGE**" should immediately follow the dosage directions.

   2. Prolonged usage should be only on the advice and direction of a physician.

   3. Pregnant or nursing mothers and those with liver or kidney disease should consult a physician before use.

   4. Due caution should be exercised when driving or operating a vehicle or potentially dangerous machinery.