FINISHED PRODUCTS OF THE 'OVER THE COUNTER' TYPE

Products consisting of therapeutic substances and excipients already used in products available on the Australian market will be considered for importation. Applications should be accompanied by:

A. Completed Form H1312 - National Register of Therapeutic Goods which must give full formulation details and listing all substances in the formulation using Australian Approved Names or chemical names if substances do not have Australian Approved Names. (Herbal ingredients by correct botanical name.) The actual amounts of each active ingredient per dosage unit in descending numerical order must also be stated. If colourings are included indicate the Colour Index Number.

B. Draft copies or mock-ups of all labelling, packaging and promotional material which it is proposed to use for distribution in Australia. Draft labels and packaging submitted must confirm to Therapeutic Goods Order No 22 described in the next section.

C. Certificate of Pharmaceutical Product for each item, issued by the Regulatory Authority in the Country of Origin.

The Commonwealth Department of Community Services and Health expects that responsibilities relating to State Health Regulations will be complied with by the importer. State Health Departments should be consulted if necessary.

Following examination of this information by the Department applicants will be advised of any further details which may be required.

LABELS

Applicants are provided with a copy of THERAPEUTIC GOODS ORDER NO 22 with which all labels and packaging for therapeutic goods marketed in Australia are expected to conform in all respects.

The Department requires that labels for all finished products imported into Australia shall include the following information in English:

1. The name of the product.

2. The names of all active ingredients in the product.