REQUIREMENTS FOR LABELLING MATERIALS OF CERTAIN CATEGORIES OF PRODUCTS CONTAINING TWO OR MORE ACTIVE INGREDIENTS

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SECTION 1. Applicability of the Provisions of AO 55 s., 1988 — All pertinent provisions of A.O. 55 s., 1988 on general requirements and specific requirements for labelling materials of pharmaceutical products shall apply to products containing two or more active ingredients covered by this A.O.

SECTION 2. Coverage — This A.O. covers only products containing two or more active ingredients belonging to the categories below:

2.1 Products containing two or more active ingredients with a single International Non Proprietary Name (INN)

2.2 Products containing two and three active ingredients but without a single INN

2.3 Fluid Replacement and Special Solution Products which follow the standard formulations contained in the current edition of the Philippine National Drug Formunaly (PNDF)

2.4 Multivitamin Products which follow the standard formulations contained in the current edition of the PNDF.

2.5 Multivitamin Products with non-vitamin components which follow the standard formulations contained in the current edition of the PNDF

All other products with two or more active ingredients outside of the categories enumerated above are not covered by this A.O.

SECTION 3. General Labelling — Products included shall be generically labelled according to the following:

3.1 Official Name of Products Containing Two or More Active Ingredients with a Single INN

The INN name of the combination product, e.g. Cotrimoxazole for the standard formulation of Sulfamethoxazole + Trimethoprim shall be adopted as the Official Name and shall be used on the label as shown below:

COTRIMOXAZOLE

(Brand Name, if any)

3.2 Official Name of Products Containing Two and Three Active Ingredients but without a Single INN

For these products, the Generic Names of the two and three active ingredients shall be adopted as the Official Name, and shall be used on the label as shown below:

FERROUS SALT FOLIC ACID

(Brand Name, if any)

FERROUS SALT + FOLIC ACID

(Brand Name, if any)

PARACETAMOL TRIPROLIDINE HCI PSEUDOEPHEDRINE HCI

(Brand Name, if any)

3.3 Official Name of Fluid Replacement and Special Solution Products which Follow the Standard Formulations Contained in the Current Edition of the PNDF

The nomenclature used by the PNDF for Fluid Replacement and Special Solution Products shall be adopted as the Official Name, and shall be used on the label as shown below:

Dextrose 5% in 0.9% Sodium Chloride

(Brand Name, if any)

Lactated Ringer's Solution

(Brand Name, if any)

Oral Rehydration Salts Replacement

(Brand Name, if any)

Peritoneal Dialysis Solution with Dextrose 4.25%

(Brand Name, if any)

3.4 Official Name of Multivitamin Products

For Multivitamin Products with standard formulations included in the current PNDF the official name adopted shall be Multivitamins with the complete listing of the vitamin content using the standard abbreviated name as shown below:

Multi-vitamins

A, B Complex, C, D, E

(Brand Name, if any)

3.5 Official Name of Products Containing other Multivitamin Standard Formulations

For other standard vitamin formulations, e.g., Vitamin B1, B6 and B12, the Official Name shall be the complete listing of the vitamin content using the standard abbreviated names, as shown below:

Vitamins B1 + B6 + B12

(Brand Name, if any)

3.6 Official Name of Multivitamin Products with Non-Vitamin Components

For other standard formulations of Multivitamin Products with non-vitamin components, the Official Name shall be Multivitamins with the name of the specific additional component(s) with the complete listing of the

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content using the standard abbreviated names, as shown below:

Multi-vitamins + Fe

A, B Complex, C, D, E, + Fe

(Brand Name, if any)

Multivitamins + Minerals

A, B Complex, C, D, E + Fe, Ca, P, Mn, Zn

(Brand Name, if any)

SECTION 4. Procedure for Changing Over to New Labels

4.1 All drug establishments that own registered drug products covered under this A.O. shall present their proposed generic labels in compliance with the above for review and approval by BFAD not later than March 31, 1990.

4.2 All satisfactory applications for new generic labels covered by this A.O. submitted within March 31, 1990 deadline shall be approved by BFAD no later than April 30, 1990.

4.3 Starting sixty (60) days after approval but not later than June 30, 1990, only such approved generic labels shall be used for these products in new production. The drug establishment is required to submit the last batch number bearing the old label and the first batch number bearing the new generic label before the start of actual production with the new label.

4.4 After September 30, 1990, all covered products with the old labels shall be deemed misbranded and subject to seizure by BFAD.

4.5 It shall be the responsibility of the drug establishment to ascertain the coverage of this A.O. on its products.

4.6 Remedial generic labelling according to the provisions of A.O. 79 s., 1989 is available to products covered by this A.O.

SECTION 5. Separability Clause — In case any provision of the A.O. is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

SECTION 6. Repealing Clause — All A.O.'s, Rules and Regulations, and other Administrative Issuances or parts thereof, inconsistent with the provisions of the A.O. are thereby repealed and modified accordingly.

SECTION 7. Effectivity and Time-Table — This A.O. shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation.

Adopted: 15 Feb. 1990

(SGD.) ALFREDO R.A. BENGZON, M.D.
Secretary

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