

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

DOH ADMINISTRATIVE ORDER NO. 85, February 15, 1990

Read online (full-text search, related cases, audio case brief): <https://batas.org/library/70304c75d643/>

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 Formulary (PNDF)

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

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

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 HCl PSEUDOEPHEDRINE HCl

(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

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

ABOUT BATAS.ORG

Study smarter at BATAS.org

The Philippine bar review and law-school companion built around how your brain actually remembers.

The complete Philippine law library - free for everyone.

More than 100,000 Supreme Court decisions, Republic Acts, and executive issuances - full-text searchable, browsable by category and year, and always free. No paywall, no login. This PDF came from it.

Audio case-brief lectures.

Any decision becomes a podcast-style lecture - facts, issues, ruling, and doctrine - with read-along highlighting and a hands-free presentation mode. Study while commuting, working out, or resting your eyes.

Bar review built on the science of memory.

Complete, sequenced courses for all eight bar subjects, narrated like podcasts and reinforced with retrieval practice and spaced review - the study techniques with the strongest evidence behind them.

The full law-school curriculum.

One subscription unlocks the entire J.D. curriculum - every subject, every lesson, with your progress tracked down to the paragraph so you can pick up exactly where you left off, on any device.

Mock exams that tell you where you stand.

Timed multiple-choice exams graded instantly, with per-subject score breakdowns and focus suggestions that point you at your weakest topics first.

A study planner that keeps you on pace.

Set your schedule and BATAS tells you every day whether you are on track for bar day - and exactly which lesson to take next.

Start free at <https://batas.org>

The law library is free forever - and your first lesson is one click away.

The text of this document is an official public record and remains in the public domain. Formatting, presentation, and compilation © 2026 batas.org.

Downloaded free from the batas.org Law Library. Share it freely - the library is free for every law student, bar reviewee, and practitioner.