REQUIREMENTS FOR LABELLING MATERIALS OF CATEGORIES OF PHARMACEUTICAL PRODUCTS CONTAINING FOUR OR MORE ACTIVE INGREDIENTS OUTSIDE THE COVERAGE OF A.O. 85, S. 1990

Read online (full-text search, related cases, audio case brief): https://batas.org/library/4cccdacdd48b/

SECTION 1. Applicability of the Provisions of A.O. 55, s. 1990 — All pertinent provisions of A.O. 55, s. 1990 on general and specific requirements for labelling materials of pharmaceutical products shall apply to products containing four or more active ingredients covered by this A.O.

SECTION 2. Coverage — All multiactive-ingredient pharmaceutical products containing four or more ingredients not covered by A.O. 85, s. 1990, are covered by this A.O.

SECTION 3. Generic Labelling — For these multiactive-ingredient products covered by this A.O., the Generic Name for each active ingredient with the corresponding strength or concentration shall be printed within the outline box on the principal display panel with the Trade or Brand Name of the product printed in smaller letters than each generic name immediately below the box as shown in the example below:

3.1 Example 1

ORAL REHYDRATION SALT — 90
Per Liter

Sodium

90 mEq

Potassium

20 mEq

Chloride

80 mEq

Citrate

30 mEq

Dextrose

25 g

PEDIALYTE — 90

3.2 Example 2

DTP + IPV iNJ.
Per 5 ml Vial

Diphtheria Toxoid

1 vac. dose:

Tetanus Toxoid

1 vac. dose:

Bordetella

Pertussis

min. int'l IU

Inactivated Polie Myelitis

Bar review courses, mock exams and a study planner that keeps you on pace - batas.org

Type 1

1 vac. dose

Type 2

1 vac. dose

Type 3

1 vac. dose

TETRACOQ

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, 1991.

4.2 All satisfactory applications for new generic labels covered by this A.O. submitted within the March 31, 1991 deadline shall be approved by BFAD not later than May 31, 1991.

4.3 Starting sixty (60) days after approval but not later than August 1, 1991, 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 new generic label before the start of actual production with the new label.

4.4 After October 31, 1991, all covered products with the old label 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 the A.O.

4.7 Approval of the new label under this new A.O. should not be taken to mean that the present formula for the FDC is acceptable. This formula will still be subject to review per A.O. 96, s. 1990.

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 this A.O. are thereby repealed and modified accordingly.

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

Adopted: 3 Dec. 1990

Study hands-free: podcast-style lessons with read-along highlighting - batas.org

(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.