CLASSIFYING PRECOMPOUNDED UNIT DOSE FORMULATIONS OF NALBUPHINE AND ITS SALTS, ISOMERS, AND SALTS OF ISOMERS AS EXEMPT PROHIBITED DRUGS

Read online (full-text search, related cases, audio case brief): https://batas.org/library/2e520e425645/

WHEREAS, precompounded unit dose formations of Nalbuphine and its salts, isomers and salts of isomers have been found being so abused as to cause a public health and social problem;

WHEREAS, there is an urgent need for preventive measures against escalation of the abuse incidence wherein these formulations are involved and for the suppression of the illicit drug supply;

WHEREAS, these formulations have therapeutic value and have to be available for their specific indications;

WHEREAS, these formulations are presently not listed in any of the Schedules under the 1961 Single Convention on Narcotic Drugs, as amended;

NOW, THEREFORE, the Dangerous Drugs Board, pursuant to its powers under Section 36 (a) of R.A. 6425, as amended, and in accordance with its decision arrived at in its meeting of _____ 1993, hereby prescribes the following:

SECTION 1. Definitions — As used in this Regulation, the terms:

1.1 Precompounded Unit Dose Formulation refers to the product which has been compounded in advance by the pharmaceutical company in accordance with Current Good Manufacturing Practice (CGMP) and does not require further manipulation by the prescribing practitioner.

1.2 Nalbuphine refers to:

INTERNATIONAL NON-PROPRIETARY NAME (INN)	CHEMICAL NAME	BRAND NAME
Nalbuphine	17-Cyclobutylmethyl-7,8- dihydro-14 hydroxy-17-normorphine	Nubain
	(-)-(5R,6S,14S)-9a-Cyclo-butylmethyl-4,5-epoxymor-phinan-3,6,14-triol	

1.3 Salts, Isomers, Salts of Isomers refers to Nalbuphine salts, isomers, and salts of isomers (whether optical, position, or geometric) which

> 1.3.1 exist within the specific chemical designation by whatever official name, common or usual name, or brand name, and

1.3.2 have the same or similar psychologic and/or physiologic effects as the parent drug.

SECTION 2. Classification — Precompounded unit dose formulations containing Nalbuphine or its salts, isomers, and salts of isomers are hereby classified as Exempt Prohibited Drugs.

SECTION 3. Requirements — As herein classified the formulations shall be subject to the following requirements:

3.1 Special Permit. A Special Permit To Import shall be secured prior to each importation. Upon arrival of the importation, other pertinent requirements of Dangerous Drugs Board under Board Regulation No. 3-A, s. 1983 shall be complied with.

3.2 Records. Importation, exportation, distribution, and sale thereof shall be recorded in an Additional Dangerous Drugs Record Book registered prior to use.

3.3 Prescription/dispensing. Prescription shall be through an ordinary prescription form wherein shall be stated the name, address, S2 license number, and PTR number of the prescribing practitioner, as well as the name, address, and age of the patient. Each prescription shall cover a maximum of thirty (30) mg. Dispensing shall not be effected except upon receipt of the properly filled up prescription form.

SECTION 4. Limitations as to Distribution — The subject formulation shall be distributed by the manufacturer, importer, compounder, producer and distributor (wholesaler) only to hospitals (including medical clinics) and BFAD registered outlets with reputation for integrity as determined by the Dangerous Drugs Board.

SECTION 5. Limitations as to the Quantity of the Formulations which Drug Outlets can Carry at any time — The Dangerous Drugs Board shall determine the quantity of Nalbuphine formulations which a drug outlet can carry at any time considering, as basis, among others, the previous legitimate annual consumption and therapeutic needs. As herein construed, "drug outlets" include hospitals and clinics (government and private).

SECTION 6. Prohibition Against Sample Distribution — The subject formulation shall not be distributed as samples to practitioners or to the general public.

SECTION 7. Limitations as to Advertising — The subject formulation may be advertised only in scientific journals limited to prescribing practitioners. In no case shall the preparations be advertised to the general public.

SECTION 8. Authority to Resolve Questions/Interpretations Regarding Classifications — The Board shall have the sole authority to resolve questions/interpretations regarding the proper classification of the formulations containing the subject drugs.

SECTION 9. Sanctions — Any violation of this Regulation shall be penalized with administrative sanctions without prejudice to criminal prosecution under Articles II and IV of R.A. 6425, as amended if warranted.

SECTION 10. Date of Effectivity — This Regulation shall take effect fifteen (15) days after completion of its publication in a newspaper of general circulation once a week for two consecutive weeks.

Adopted: 20 May 1993

(Sgd.) JUAN M. FLAVIER
Chairman
Secretary of Health

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

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.