UNITED NATIONS

E/NL.1993/45-47
21 January 1994

ENGLISH ONLY*

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

PHILIPPINES

Communicated by the Government of the Philippines

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

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V.94-20360

E/NL.1994/45

BOARD REGULATION
NO. 1, S. 1992

17 June 1992

SUBJECT: AMENDING SECTION 3, PARAGRAPH (d) OF BOARD REGULATION NO. 1, S. 1987

Pursuant to the powers vested in the Dangerous Drugs Board under Section 36(a) of R.A. 6425, as amended, Section 3, paragraph (d), of Board Regulation No. 1, S. 1987, is hereby amended to read as follows:

d. Prescription/Dispensing

1. In prescribing the exempt benzodiazepines, only one drug per prescription shall be made. The pharmacologic category of exempt benzodiazepine shall be indicated by the prescriber either as hypnotic or anxiolytic or both which shall be based on the classification approved by the Board. The number of tablets or capsules prescribed in one prescription shall be based on the judgment of the prescribing practitioner (physician, dentist, veterinarian) but in no case shall the total exceed the following limits:

a) for anxiolytic preparations - four (4) weeks supply for the patient or one hundred (100) tablets/capsules, whichever limit is more restrictive.

b) for hypnotic preparations - two (2) weeks supply or thirty (30) tablets/capsules, whichever limit is more restrictive.

c) where the preparation is prescribed as anxiolytic as well as hypnotic in one prescription, the limit set for hypnotics shall apply.

d) for preparations in ampuls prescribed as anxiolytic or hypnotic or both - three (3) ampuls x 2mL or one (1) ampul x 10mL per ampul except when such preparations are for hospital use in which case the ampuls shall be placed in the custody of the appropriate hospital personnel.

2. Prescriptions for exempt benzodiazepines shall be dispensed through ordinary prescription wherein the following shall be indicated:

a) Date of prescription

b) Name and address of the prescribing practitioner

c) Privilege Tax Receipt (PTR) Number of the prescribing practitioner

d) Dangerous Drugs License Number (S2) of the prescribing practitioner

e) License (PRC) Number of the prescribing practitioner

f) Name, age and address of the patient

g) Generic name of the drug (immediately followed by the strength of its principal active ingredient if the drug is a preparation)

h) Brand name(s) may be indicated below by the generic name

i) Total number of the units to be supplied in words followed by its equivalent in Roman numerals enclosed in parentheses

j) Direction for use and the words "Non-Refillable". The use of the words "As directed" or other statements to the said effect in lieu of the directions for use is not allowed.

k) Signature of the practitioner

This amendment shall take effect upon its publication once a week for two (2) consecutive weeks in a newspaper of general circulation.

TOMAS P. MARAMBA, JR., M.D., M.H.A.
Acting Chairman
(Undersecretary of Health
for Standards and Regulation)

ATTESTED.

MANUEL M. SUNNET, CESO II
Executive Director
and Board Member

E/NL.1994/46

BOARD REGULATION
NO. 2, S. 1992

December 17, 1992

SUBJECT: AMENDING BOARD REGULATION NO. 16, S. 1973, BY PROVIDING THE CRITERIA FOR DECLASSIFYING DANGEROUS DRUGS AND DANGEROUS DRUG PREPARATIONS WHICH ARE NOT UNDER INTERNATIONAL CONTROL

Pursuant to its powers under Section 36(a) of Republic Act 6425, as amended, the Dangerous Drugs Board hereby prescribes the following:

SECTION 1. Criteria for Removal (Delisting) - dangerous drugs and dangerous drug preparations not under international control may be removed from the list of dangerous drugs, when as determined by the DDB, the following conditions exist:

1.1 there is sufficient and documented proof of the safety of the dangerous drugs and dangerous drug preparations;

1.2 absence of any report of abuse;

1.3 If a preparation:

1.3.1 none of its ingredients produces a synergism which results in enhancing the abuse liability of the preparation

1.3.2 it consists of a single psychotropic substance in dosage form, and is compounded with non-psychotropic or non-narcotic substances which have antagonistic or reductive effect on the abuse liability of the preparation.

1.3.3 it has a high therapeutic usefulness

1.3.4 the ingredients of the dangerous drug or dangerous drug preparation are not included in the listings of narcotics and psychotropic substances controlled under international and foreign agreement to which the Philippine Government is a signatory such as:

1.3.4.1 List of Narcotic Drugs under the Single Convention of 1961, as amended by the 1972 Protocol

1.3.4.2 List of Psychotropic Substances under the Vienna Convention of 1971

1.3.4.3 The 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

SECTION 2. Procedural requirements governing delisting when petitions from appropriate agencies are received: - The following procedures shall be followed:

2.1 The petitioner shall submit a written request to the DDB accompanied by documented proofs that the dangerous drugs and dangerous drug preparations meet the criteria under Section 1 hereof.

2.2 The Board shall determine if the dangerous drugs or dangerous drug preparations sought to be delisted amply fills the requirements for delisting, and in the process, may hold public hearings if such are deemed necessary.

2.3 If the Board is satisfied that the conditions for removal are fully met, the appropriate regulation shall be issued and the publication thereof made in accordance with the provisions of Section 40, R.A. 6425, as amended.

SECTION 3. The Provisions of Section 2 hereof notwithstanding, the Board may on its own initiate proceedings for removal of dangerous drugs and dangerous drug preparations not under international control from the controlled lists.

SECTION 4. This Regulation shall take effect after the completion of its publication once a week for two (2) consecutive weeks in a newspaper of general circulation.

JUAN M. FLAVIER, M.D., M.P.H.
Chairman
(Secretary of Health)

ATTESTED:

Atty. MANUEL M. SUPNET, CESO II
Executive Director & Board Member

E/NL.1994/47

BOARD REGULATION
NO. 3, S. 1992

SUBJECT: CLASSIFYING NALBUPHINE RAW MATERIAL AS REGULATED DRUG AND ITS PREPARATION AS EXEMPT REGULATED, SUBJECT TO CERTAIN CONDITIONS

SECTION 1. Pursuant to the powers vested in it under Section 36(a) of R.A. 6425, as amended, the Dangerous Drugs Board, having found after evaluation that the substance Nalbuphine has the capacity to produce dependency and is likely to be so abused as to constitute a public health and social problem, hereby classifies any raw material, compound containing the following substance or its salts, isomers and salts of isomers (whether optical, position or geometric) which

(a) exist within the specific chemical designation by whatever official name, common or usual name or brand name, and

(b) have the same or similar psychologic and/or physiologic effects as the parent drug,

as Regulated Drug. Any preparation containing Nalbuphine substance as described above is classified as Exempt Regulated.

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

SECTION 2. As so classified, the raw material shall be subject to the following requirements:

2.1 Importation, distribution and sale thereof shall be posted/entered in the Dangerous Drug Record Book to be registered prior to use.

2.2 Importation shall be subject to an Import Certificate/ Permit and requirements of the Dangerous Drugs Board under B.R. No. 3-A, S. 1983 (SUBJECT: Procedures to be followed by Importers of Dangerous Drugs and Exempt Preparations in the Philippines).

SECTION 3. Any preparation classified as Exempt Regulated shall be subject to the following requirements:

3.1 Importation shall be subject to a Special Permit and requirements of DDB under B.R. No. 3-A, s. 1983.

3.2 Importation, exportation, distribution and sale thereof shall be posted/entered in the Additional Dangerous Drugs Record Book to be registered prior to use.

3.3 Prescription/Dispensing shall be through an Ordinary Prescription wherein shall be stated the name, address, S-2 license number, and PTR No. of the prescribing practitioner, as well as the name, address and age of the patient.

SECTION 4. The drug preparation 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, upon approval by the DDB.

SECTION 5. Dispensing Requirements. - In dispensing Nalbuphine preparation a maximum of three (3) ampuls per prescription shall be allowed.

SECTION 6. Drug outlets shall procure Nalbuphine preparation. However, at any time the drug in their possession shall not exceed the following quantities:

Hospital	- 100 ampuls
Medical Clinic	- 10 ampuls
Reputable Drugstore	- 50 ampuls

SECTION 7. Prohibition against sample distribution. - The preparation shall not be distributed as samples to physicians or to the general public.

SECTION 8. Prohibition against advertising. - It shall not be advertised to the general public but only through scientific journals.

SECTION 9. Reports required. - Importers, manufacturers, compounders, producers and distributors of Nalbuphine raw materials/preparations shall render to the Board monthly report about their product containing the following data:

1. Stock on hand at the beginning of the period;
2. Date of importation/manufacture/distribution/ purchase;
3. Quantity of importation/manufacture/distribution/ purchase;
4. Import Certificate #/Special Permit #/Local Purchase Order #/Official Receipt # covering Importation/ Manufacture/Distribution/Purchase;
5. Total stock for the month;

6. Quantity disposed of;
7. Balance on hand at the end of the period.

SECTION 10. Period of Effectivity. - This Regulation shall be effective for a period of six (6) months. If at anytime within this period there is evidence concerning rampant abuse of the drug as to constitute a public health and social problem as determined by the Board, Nalbuphine preparation shall automatically be categorized as a Regulated Drug.

Such automatic categorization, however, shall be published in a newspaper of general circulation twice a week for two (2) consecutive weeks.

SECTION 11. Sanctions. - Any violation of this Regulation shall be penalized with administrative sanctions without prejudice to criminal prosecution under Article III of R.A. 6425, as amended.

SECTION 12. 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.

JUAN M. FLAVIER, M.D., M.P.H.
Chairman
(Secretary of Health)

ATTESTED:

Atty. MANUEL M. SUPNET, CESO II
Executive Director & Board Member