

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

DDB BOARD REGULATION NO. 2 s. 1992, December 17, 1992

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December 17, 1992

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.

Adopted: 17 Dec. 1992

(Sgd.) JUAN M. FLAVIER, M.D., M.P.H.
Chairman

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