NATIONAL ADMINISTRATIVE REGISTER · [DDB BOARD REG. NO. 9, OCTOBER 19, 1989]

EXEMPT REGULATED PREPARATIONS

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Pursuant to the powers of the Dangerous Drugs Board under Section 36(a), Article VIII of R.A. 6425, as amended, the following regulation is hereby prescribed:

SECTION 1. Definition of Terms —

a. Dangerous Drug Preparation — refers to any solution or mixture, in whatever physical state, containing:

a.1 one or more dangerous drugs: or

a.2 one or more dangerous drugs in dosage form.

As herein construed a dangerous drug preparation is in dosage form when it consists of a measured, small quantity of dangerous drugs or a combination of dangerous drugs in whatever form (tablet or pill, ampul or powder) ready for consumption by, or administration to, a patient or animal, whether orally or parenterally or through other routes.

b. Exempt Dangerous Drug Preparation — is any dangerous drug preparation which is compounded in such a way that it presents no, or a negligible, risk of abuse and the dangerous drug it contains cannot be recovered by readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem; and has high therapeutic value a wide use for legitimate purposes and is a much needed medicine required to be easily available to the public in medical need thereof. The word compounded as herein used means the process of combining a controlled drug with a non-controlled ingredient counteractive of the abuse liability of the controlled drug present.

b.1 Exempt Regulated Drug Preparation — is any dangerous drug preparation which:

b.1.1 contains only one regulated drug internationally controlled under Schedule III or IV of the 1971 Convention on Psychotropic Substances and not exceeding the quantitative limits for such as determined by the Board:

b.1.2 is not a combination of a regulated drug with a prohibited drug:

b.1.3 is not a combination of a psychotropic drug under international control with an uncontrol drug having similar psychotropic properties;

b.1.4 does not contain any psychotropic substance listed in Schedule II annexed to the 1971 Convention on Psychotropic Substances;

b.1.5 includes one or more non-narcotic or non-psychotropic active medicinal ingredients in proportion sufficient to confer upon the preparation valuable medicinal properties other than those possessed by the regulated drug alone and to prevent enhancement potentiation or synergism of the abuse liability of the regulated drug (or any of its salts) that it contains; or if it consists of a single psychotropic substance in dosage form, is compounded with a counteracting non-psychotropic or non-narcotic material;

b.1.6 is devoid of any prohibited drug under Schedule IV of the 1961 Convention on Narcotic Drugs or another psychotropic drug not under domestic or international control but with known abuse potential; and

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b.1.7 is not in injectable form.

This last criterion does not apply when the preparation has high therapeutic usefulness. As herein construed, a preparation in injectable form is deemed to have high therapeutic usefulness if it is very effective for the indicated use, is safely administered by skilled professionals and is widely used in medicine.

SECTION 2. Jurisdiction . — The Dangerous Drugs Board has jurisdiction and control over all exempt dangerous drug preparations except where registration of the product and determination of its efficacy, purity and safety are concerned which are within the functions of the Bureau of Food and Drugs under R.A. 3720, as amended.

SECTION 3. Control Masures Not Required for Exempt Regulated Preparations. — Exempt regulated preparations are not subject to the following control measures:

a. Compulsory use of DDB Form 1-72 or Yellow Prescription.

The preparation shall, however, be prescribed through an Ordinary Prescription wherein the S-2 license of the practitioner shall be indicated.

b. Recording in the Dangerous Drugs Record Book.

The preparation should, however, be recorded in the Additional Dangerous Drugs Record Book.

SECTION 4. Effect of the Presence of a Prohibited Drug . — When the exempt regulated preparation is compounded with a prohibited drug, the preparation shall be deemed to be a prohibited drug.

SECTION 5. Prohibition Against Sample Distribution. —

SECTION 6. Advertising . — Exempt dangerous drug preparations may be advertised in scientific journals. In no case, however, shall such preparations be advertised to the general public.

SECTION 7. Sanctions . — Any individual or entity found, after notice and hearing, guilty of violating this regulation shall be penalized with the sanctions embodied in Section 36(1), Article VIII of Republic Act No. 6425, as amended, without prejudice to the institution of criminal proceedings if circumstances so warrant.

SECTION 8. Repealing Clause . — All regulations inconsistent herewith are hereby repealed or modified accordingly.

SECTION 9. Effectivity . — This Regulation shall take effect after the completion of its publication in the Official Gazette and in a newspaper of general circulation once a week for two (2) consecutive weeks, whichever is earlier.

Adopted: 19 Oct. 1989

(SGD.) THOMAS P. MARAMBA, JR., M.D., M.H.A.
Vice-Chairman
(Undersecretary of Health for Standard and Regulation)

Effective: November 28, 1989

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