



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 31
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF GREPCORE DIAMONDE, INC.

WHEREAS, under Section 81 (b) and (r) of Article IX of RA 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002, the Board issued Board Regulation No. 3, Series of 2003 which provides for the “Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with any Dangerous Drugs, Controlled Precursors and Essential Chemicals and other Similar or Analogous Substances”;

WHEREAS, GREPCOR DIAMONDE INC. with business address at 14A 3RD ST. New Manila, Quezon City, Philippines is seeking exemption from regulatory measures for the following products:

1. Dimension ® system METH (Methadone) FLEX ® Reagent cartridge - <0.001 %
Methodone Conjugate
2. Dimension ® system AMPH (Amphetamine) ® Reagent cartridge –0.0012%
Amphetamine Antibody;0.0006% Methamphetamine Antibody
3. Dimension ® system COC (Cocaine) FLEX ® Reagent cartridge
4. OPI (Opiate) FLEX ® Reagent cartridge - <0.001% Opiate Conjugate
5. PCP (Phencyclidine) FLEX ® Reagent cartridge - <0.001% PCP Conjugate
6. THC (Cannabinoids) FLEX ® Reagent cartridge - <0.001 THC Conjugate
7. BARB (Barbiturate) FLEX ® Reagent cartridge - <0.001% Barb Conjugate
8. BENZ (Benzodiazepines) FLEX ® Reagent cartridge - <0.001 Diazepam Conjugate
9. ADVIA CENTAUR FT4, 250 TEST (REF) – 1.03% Barbitol Sodium
10. IMMULITE ® 1000 Phenobarbital – 7.013% Phenobarbital Reagent Wedge
11. IMMULITE ® 2000 Phenobarbital - 7.013% Phenobarbital Reagent Wedge
12. PHNO Flex Reagent Cartridge – 0.03% PHNO MAB In-vitro
13. ADVIA CENTAUR FT4, 50 TEST (REF) – 1.03% Barbitol Sodium
14. DC85 DIMENSION IRON CALIBRATOR (Level 2 & Level 3 Vista Level A) - 0.1312%
Hydrochloric Acid (HCL)

WHEREAS, Section 4(2-d, e & f), Article II of the same Regulation also provides that the Board may exempt from specific measures of regulatory control requirements any preparation with liquid chemical mixture containing less than 30% by weight of the Table II chemical; or solid, semisolid and highly viscous chemical mixture containing Table II chemical; or when the Board is satisfied that the mixture is formulated in such a way that the controlled chemical cannot be easily used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered;

WHEREAS, to assist the Board in evaluating requests for exemption, it promulgated Board Resolution No.1 Series of 2008 entitled “**Creating a Technical**

Working Group (TWG) to assist the Board in considering request of Manufacturers and Importers of finished products from specific measures of regulatory control requirements”;

WHEREAS, it has been determined by the DDB Technical Working Group (TWG) that **GREPCOR DIAMONDE INC.** foundation were laid in 1995 when the company started the marketing and distribution of the first diagnostic products. In 2008, it became the exclusive distributor of Siemens Healthcare Diagnostics in the Phils. and in 2010 Grepcor secured the exclusive distributorship for Alere’s Oncology Line and Women’s Health. It is duly registered with PDEA and handler of **S5I-02165001-R025 dated 29 August 2012 and valid until 27 August 2013;**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **GREPCOR DIAMONDE INC.** products containing controlled chemical less than the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(a, b, c, d, & e);

WHEREAS, after satisfying the requirements under the above mentioned regulations, **GREPCOR DIAMONDE INC.’** products are no longer covered by the provisions of **Section 10 (Application for import, export or transit permits), Section 11 (Grant of import, export or transit permits), and Section 22 (Licensed operators NOT to deal with unlicensed operators) of BR No.3, S. 2003;**

WHEREAS, during the Caucus of the Board held on 12 December 2012, the matter was presented and was eventually unanimously approved in principle by those in attendance, subject to confirmation by the Board at its next regular meeting;

WHEREAS, in order to facilitate its confirmation, the said matter, along with the other concerns approved in principle during the Caucus, was subjected to an Ad Referendum, which was thereafter signed by at least nine (9) Members of the Board constituting a quorum on January 16, 2013.

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED, GRANTING EXEMPTION** and the issuance of a Board Resolution, which shall be valid for one (1) year unless revoked, to **GREPCOR DIAMONDE INC.’** products that contain controlled chemical below the 30% threshold of the Table II chemicals, in accordance with the following provisions of Section 4-2(d & f).

a. That the above cited exemptions shall still be subject to the following conditions:

- (1) The **GREPCOR DIAMONDE INC.** shall secure a license from the PDEA and comply with the reporting requirements as provided for in Board Regulation No. 3, Series of 2003;
- (2) The Board shall strictly monitor subject finished products from their importation to distribution to end-users;
- (3) The DDB-PDEA Monitoring Team shall have free access to the **GREPCOR DIAMONDE INC.** premises where the finished products are kept and/or used;
- (4) The **GREPCOR DIAMONDE INC.** shall assume full responsibility for any misuse of the imported finished product, caused either by its own negligence or by negligence of all persons acting under their name or control and supervision; and

- (5) Any violation of the provisions of Board Regulation No. 3, Series of 2003, shall be a ground for the revocation of the certificate of exemption at anytime and would be dealt with severely.

APPROVED and ADOPTED this 16th day of January, in the year of Our Lord, 2013 in Quezon City.

(Sgd) **Secretary ANTONIO A. VILLAR, JR.**
Chairman, Dangerous Drugs Board

Attested:

(Sgd) **Assistant Secretary AMADOR S. PABUSTAN**
OIC-Secretary of the Board