Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
3/F, DDB – PDEA Building, NIA Road, National Government Center, East Triangle, Diliman, Quezon City, Philippines
P.O Box No. 3682 Manila, Tel. No. 929-1753, Telefax 929-1546, Website: www.ddb.gov.ph, E-mail: info@ddb.gov.ph

BOARD RESOLUTION NO. 46
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCT OF GREPCOR 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 product **AFINION ™ ACR CONTROL containing <0,6% 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.** product containing controlled chemical less than the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d);

WHEREAS, after satisfying the requirements under the above mentioned regulations, **GREPCOR DIAMONDE INC'S** product is 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.**

WHEREFORE, be it **RESOLVED,** as it is hereby **RESOLVED:**

a. **TO GRANT 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 provisions of Section 4-2(d & f).

b. 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 product 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 product is 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 17th 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