Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 114
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF BIOSYSTEMS REAGENTS & INSTRUMENTS

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, BIOSYSTEMS REAGENTS & INSTRUMENTS with business address at 74 Sct. Dr. Lazcano, Laging Handa, Quezon City, Philippines is seeking exemption from specific measures of regulatory control requirements to the following products listed hereunder:

1. **Phosphorus Kit with Component A containing 3.5% Sulfuric Acid (H2SO4)**
2. **Phosphorus Kit with Component B containing 3.5% Sulfuric Acid (H2SO4)**

WHEREAS, Section 4(2-c, 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 when the Table II chemical is a normal ingredient in consumer goods or finished products; or 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 **BIOSYSTEMS REAGENTS & INSTRUMENTS** is a subsidiary of Biosystems SA from Barcelona Spain and is the manufacturer of both reagents and equipments used to measure the phosphorus level in human. The company is a handler of PDEA License **P5IM-03751001-N007 dated 15 March 2013 and valid until 05 March 2014 as importer/end-user of controlled chemicals**;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of BIOSYSTEMS REAGENTS & INSTRUMENTS' products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d, e & f);

WHEREAS, after satisfying the requirements stipulated under the above mentioned regulations**, BIOSYSTEMS REAGENTS & INSTRUMENTS' 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) and of BR No.3, S. 2003.**

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

TO GRANT EXEMPTION and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to **BIOSYSTEMS REAGENTS & INSTRUMENTS'** above mentioned products containing Toluene**,** a controlled chemical that are below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(f).

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

   (1) The BIOSYSTEMS REAGENTS & INSTRUMENTS shall secure a license from 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 BIOSYSTEMS REAGENTS & INSTRUMENTS premises where the finished products are kept and/or used;

   (4) The BIOSYSTEMS REAGENTS & INSTRUMENTS 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 6th day of May , in the year of Our Lord, 2013 in Pampanga.

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

Attested:

(Sgd.) **Undersecretary JOSE MARLOWE S. PEDREGOSA**
Secretary of the Board