Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 76
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED

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, SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED with business address at Unit 502 Metrostar Bldg. 1007 Metropolitan Ave., Makati City Philippines is seeking exemption from regulatory measures for the following products, to wit:

1. **ABX Pentra Bilirubin Direct CP with Reagent 2 containing 1 -5% Hydrochloric Acid**
2. **ABX Pentra Bilirubin Direct CP with Reagent 1 containing 1 -5% Hydrochloric Acid and Reagent 2 containing <1% Hydrochloric Acid**
3. **ABX Pentra Phosporus CP with Reagent containing <2.2% Sulfuric Acid**
4. **ABX Basolyse II 1L with Reagent containing <5% Hydrochloric Acid**
5. **ABX Basolyse 5L with Reagent containing <5% Hydrochloric Acid**
6. **ABX Pentra Calcium CP with Reagent containing <0.5% Hydrochloric Acid**

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, Immunoassay Drug test kits were granted exemption by the Board having Board Resolution No. 18, s. 2004 as an example. Considering that this type of reagents/products could not be extracted and contains no or miniscule amount of dangerous drugs/controlled chemicals, thus these products present no or negligible risk of abuse; necessary for medical or scientific purposes and for the interest of the public;

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 **SCIENTIFIC BIOTECH SPECIALTIES** (**SBSI)** is a diagnostic firm dedicated to help develop an excellent healthcare system in the Phils.,and began its operation for sales and marketing on September 23, 1998. In 2005, the company devoted in the development and strengthening of its Hematology, Chemistry, Tissue Typing, Applied Science and Coagulation Markets. It is duly registered with **PDEA and handler of P5I- 03335001 as importer/distributor. License was issued on 22 November 2012 and valid until 21 November 2013;**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** finished products that contain controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(a, b, c, d, e & f);

WHEREAS, after satisfying the requirements stipulated under the above mentioned regulations**, SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED products are no longer covered by the provisions of Section 10 (Application for import, export or transit permits), and Section 11 (Grant of import, export or transit permits), 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:**

a. **TO GRANT EXEMPTION** and the issuance of Board Resolution of Exemption, which **shall be valid for one (1) year unless revoked**, to **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED' products** containing controlled chemicals 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) That **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** shall secure a license from the PDEA and comply with the reporting requirements for the raw materials used in the manufacture of the products as provided for in Board Regulation No. 3, Series of 2003;

(2) The Board shall strictly monitor subject finished products from their manufacture to distribution to end-users;

(3) The DDB-PDEA Monitoring Team shall have free access to **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** premises where the finished products are kept and/or used;

(4) That **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** shall assume full responsibility for any misuse of the imported finished products, 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