



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 2
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF 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. Metropolitan Avenue Sta. Cruz, Makati City,** Philippines is seeking exemption from regulatory measures for the following products listed hereunder:

1. **ABX Pentra Bilirubin Direct CP – 1- 5% Hydrochloric Acid (Reagent 2)**
2. **ABX Pentra Bilirubin Total CP (Reagent 1) – 1- 5% Hydrochloric Acid (HCL); (Reagent 2) -<1% Hydrochloric Acid (HCL)**
3. **ABX Pentra Phosphorus CP – <2.2% Sulfuric Acid (H2SO4)**
4. **ABX Basolyse 5L – <5% Hydrochloric Acid (HCL)**
5. **ABX Basolyse II 1L - <5% Hydrochloric Acid (HCL)**
6. **ABX Pentra Calcium CP - <0.5% Hydrochloric Acid (Reagent 2)**

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 **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED I** is a diagnostic firm dedicated to help develop an excellent healthcare system in the Phils. on July 14, 1998. SBSI is present in all parts of the Phils. directly or indirectly providing sales and

logistic services. The company is duly registered with PDEA and handler of PDEA License **P5I-03335001-N005 as importer/distributor. Said license was issued on 21 Nov. 2011 and valid until 11 Nov. 2012;**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** products 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 evaluation, the Technical Working Group (TWG) opined that the finished products containing controlled chemicals that are above the 30% threshold of Table II chemicals can be given exemption, due to having satisfied the conditions as provided for in Section 4-2(f);

WHEREAS, after satisfying the requirements under the above mentioned regulations, **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED'S** 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.**

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 **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** products that contain 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) The **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** 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 **SCIENTIFIC BIOTECH SPECIALTIES INCORPORATED** premises where the finished products are kept and/or used;
 - (4) The **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 31st day of January, in the year of Our Lord, 2012 in Quezon City.

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

Attested:

(Sgd) **Undersecretary JORGE G. NECESITO**
Secretary of the Board