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
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BOARD RESOLUTION NO. 128
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF BIOCARE HEALTH RESOURCES

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, BIOCARE HEALTH RESOURCES with business address at **#64 Web-Jet Bldg. Quezon Avenue, Quezon City, Philippines** is seeking exemption from regulatory measures to the following products/reagents containing controlled chemicals, to wit:

1. **Isovitalex Enrichment – 1% Hydrochloric Acid (HCL)**
2. **Gram Decolorizer – 25% Acetone**
3. **DMACA Indole Reagent Dropper – 11.5% Hydrochloric Acid (HCL)**

WHEREAS, Section 4(2c,-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 **BIOCARE HEALTH RESOURCES** is a major and reliable suppliers for immunology, blood banking, blood chemistry and immune-serological testing for medical laboratories. The company is now considered as among the top five (5) companies in the local diagnostic industry, noteworthy to point out that it is the only Filipino company enjoying leadership in some market niches.. **It is duly registered with** PDEA and handler **of P5I-03581001 dated 17 August 2012 and valid until 01 September 2013;**

WHEREAS, after satisfying the requirements under the above mentioned regulations**,** that **BIOCARE HEALTH RESOURCES products are no longer covered by the provisions of Section 10 and 11 (products are exempted in applying for import, export or transit permits), and Section 22 (end-users and retailers of such products are exempted from acquiring P License from PDEA) of BR No.3, S. 2003.**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of that **BIOCARE HEALTH RESOURCES' S products** that are below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d & f);

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

a. **TO GRANT EXEMPTION** and the issuance of a Certificate of Exemption, which shall be valid for one (1) year unless revoked, to that **BIOCARE HEALTH RESOURCES** 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 be subject to the following conditions**:

(1) The, **BIOCARE HEALTH RESOURCES** shall secure a license from the PDEA and comply with the reporting requirements for the raw materials 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 **BIOCARE HEALTH RESOURCES** premises where the finished products are kept and/or used;

(4) The, that **BIOCARE HEALTH RESOURCES** 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 18th day of October, in the year of Our Lord, 2012 in Quezon City.

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

Attested:

(Sgd.) **Assistant Secretary BENJAMIN P. REYES**
OIC-Secretary of the Board