Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 148
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF CRESTLINE SCIENTIFIC 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, CRESTLINE SCIENTIFIC INCORPORATED with business address at 2113 Volta St., San Isidro Village, Makati City, Philippines is seeking exemption from regulatory measures for the following products listed hereunder:

1. **HBsAg EIA Test Kits with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
2. **HBsAb EIA Test Kits with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
3. **Anti-HBc EIA Test Kits with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
4. **HBcAg EIA Test Kits with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
5. **HBcAb EIA Test Kits with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
6. **HAV IgM EIA Test KITS with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
7. **HAV IgG EIATest KITS with Stop Solution (6ml), 2N Sulfuric Acid containing 5 – 6% Sulfuric Acid**
8. **T3 EIA Test Kit with Stop Solution containing 1.7% Hydrochloric Acid**
9. **T4 EIA Test Kit with Stop Solution containing 1.7% Hydrochloric Acid**
10. **f- T3 EIA Test Kit with Stop Solution containing 1.7% 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, 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 **CRESTLINE SCIENTIFIC INCORPORATED** is involved in the importation, marketing and sale of diagnostic reagents and kits, laboratory equipment and supplies, medical and surgical and other medical devices and laboratory instruments. It was conceptualized in the early 1990 by a surgeon who is currently based in America. The company is handler **of PDEA License P5I-03397001-N004 as importer of PECS. It was issued on 1 Feb. 2013 and valid until 24 January 2014;**

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **CRESTLINE SCIENTIFIC 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, **CRESTLINE SCIENTIFIC INCORPORATED** 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 **CRESTLINE SCIENTIFIC 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 **CRESTLINE SCIENTIFIC 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 **CRESTLINE SCIENTIFIC INCORPORATED** premises where the finished products are kept and/or used;

   (4) The **CRESTLINE SCIENTIFIC 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 11th day of July , in the year of Our Lord, 2013 in Quezon City.

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

Attested:

(Sgd) **JOSE MARLOWE S. PEDREGOSA**
UNDERSECRETARY-Executive Director
Secretary of the Board