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. 116
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCT OF MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.

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, MARSMAN DRYSDALE MEDICAL PRODUCTS, with business address at G/F Molave Building, 2332 Chino Roces Avenue, Makati City, Philippines is seeking exemption from regulatory measures to the product/reagent **BECKMAN COULTER ACCESS FOLATE with FOLATE ASCORBATE (Compartment R1b) containing <1% Hydrochloric Acid (HCL);**

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 **MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.** started its operation under Marsman Drysdale Corp., Medical Products Division in 1990. It was set up as distribution arm for all products of Coulter Electronic (HK) Ltd. and re-entered the local market for automated instrument in the field of hematology, Immunology and Particle Characterization. And re-entered the local market for automated instrument in the field of hematology, Immunology and Particle Characterization. It is duly registered with PDEA and handler of **P5I-01552001-R032 License as Importer of controlled chemicals issued on 07 November 2012 and valid until 31 January 2014**

WHEREAS, after satisfying the requirements under the above mentioned regulations**, MARSMAN DRYSDALE MEDICAL PRODUCTS, INC. product is 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 **MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.'S reagent/product** that is 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 **MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.** reagent/product that contains 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 **MARSMAN DRYSDALE MEDICAL PRODUCTS, INC.** 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 Marsman Drysdale Medical Products, Inc. premises where the finished product is kept and/or used;

(4) The Marsman Drysdale Medical Products, Inc. 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