Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 18
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF MEDICAL CENTER TRADING CORPORATION

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, MEDICAL CENTER TRADING CORPORATION with business address at Pioneer St. Cor. Shaw Blvd. Pasig City**,** Philippines is seeking exemption from regulatory measures for the following products containing controlled chemicals listed hereunder:

1. **Randox Inorganic Phosphate (PH3872) – 0.37% Sulfuric Acid**
2. **Randox Total Bilirubin (T BIL) (BR 3859) – 0.47% Hydrochloric Acid**
3. **Randox Direct Bilirubin (D BIL) (BR 3807) - 0.47% Hydrochloric Acid**
4. **Randox Bilirubin (BIL) (BR411) – 0.235% 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 MEDICAL CENTER TRADING CORPORATION** began as a modest provider of pharmaceutical and basic surgical implements to the country's medical and healthcare industries. It was established on April 1946. The company is handler of PDEA License **P5I-00614001-R017/ P5C-00614001-R033 dated 27 February 2012 and valid until 22 February 2013.** The company is authorized to import, compound/manufacture PECS.

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **MEDICAL CENTER TRADING CORPORATION** finished products that contain controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d, e & f);

WHEREAS, after satisfying the requirements stipulated under the above mentioned regulations**, MEDICAL CENTER TRADING CORPORATION' 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;**

WHEREAS, during the Caucus of the Board held on 12 December 2012, the matter was presented and was eventually unanimously approved in principle by those in attendance, subject to confirmation by the Board at its next regular meeting;

WHEREAS, in order to facilitate its confirmation, the said matter, along with the other concerns approved in principle during the Caucus, was subjected to an Ad Referendum, which was thereafter signed by at least nine (9) Members of the Board constituting a quorum on January 16, 2013.

WHEREFORE, be it **RESOLVED,** as it is hereby **RESOLVED, GRANTING EXEMPTION** and the issuance of Board Resolution of Exemption, which **shall be valid for one (1) year unless revoked**, to **MEDICAL CENTER TRADING CORPORATION' products** containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the following provisions of Section 4-2(d& f).

a. That the above cited exemptions shall still be subject to the following conditions:

(1) That **MEDICAL CENTER TRADING CORPORATION** 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 **MEDICAL CENTER TRADING CORPORATION** premises where the finished products are kept and/or used;

(4) That **MEDICAL CENTER TRADING CORPORATION** shall assume full responsibility for any misuse of the imported finished product, 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 16th day of January , in the year of Our Lord, 2013 in Quezon City.

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

Attested:

(Sgd) **Assistant Secretary AMADOR S. PABUSTAN**
OIC-Secretary of the Board