

## Republic of the Philippines

Office of the President

## DANGEROUS DRUGS BOARD

## BOARD RESOLUTION NO. <u>263</u> Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCT OF SLICKCHEM 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, SLIKCHEM INC. with business address at D01-44 San Vicente St., San Vicente, San Pedro, Laguna, Philippines is seeking exemption from specific measures of regulatory control requirements for the product MURIATIC ACID- POOL CLEANER containing 29% Hydrochloric Acid;

WHEREAS, Section 4(2-c, 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 containing a controlled chemical mixture, when the Table II chemical is a normal ingredient in consumer goods or finished products that were packaged for retail sale for personal use, such as epoxies, vinyl lacquer, contact cements, plastic adhesives, waxes, cleaning agents; or 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 SLIKCHEM INC. was created in 2004 with the acquisition of the products to the former First Clean Chemical Phils. Inc. It is owned by Sydenham Laboratories which was established in 1971 by group of physicians that focuses on pharmaceutical products. It is duly registered with PDEA and handler of P5C-02225001-R033 dated 14 Aug. 2013 and valid until 07 Sept. 2014 as compounder/manufacturer of controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of SLIKCHEM INC. products that contain

controlled chemicals less than the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d):

WHEREAS, after satisfying the requirements under the above mentioned regulations, SLIKCHEM INC. product is no longer covered by the provisions of Section 22 (Licensed operators NOT to deal with unlicensed operators) and Section 39 (Controlled Chemical Registers) 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 of Exemption, which **shall be valid for one (1) year** unless revoked, to **SLIKCHEM INC.** above-mentioned product that contains controlled chemical below the 30% threshold of the Table II chemical, in accordance with the provisions of Section 4-2(d & f).
- b. That the above cited exemption shall still be subject to the following conditions:
  - (1) That **SLIKCHEM INC.** shall secure a license from PDEA and comply with the reporting requirements for the raw materials used in the manufacture of the product containing controlled chemicals as provided for in Board Regulation No. 3, Series of 2003.
  - (2) The Board shall strictly monitor subject product/chemical from their importation to end-user;
  - (3) The DDB-PDEA Monitoring Team shall have free access to **SLIKCHEM INC.** premises where the product/chemical is kept and/or used:
  - (4) That **SLIKCHEM INC.** shall assume full responsibility for any misuse of the imported products/chemicals, 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 Board Resolution on exemption at anytime and would be dealt with severely.

**APPROVED and ADOPTED** this <u>12<sup>th</sup></u> day of <u>September</u>, 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