



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 13
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF LEBENZ ENTERPRISES

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, LEBENZ ENTERPRISES with business address at 19 Bo. Malabo, Valenzuela City, Philippines is seeking exemption from specific regulatory control measures of the following products containing controlled chemicals listed hereunder:

- 1. Young’s Nail Polish Remover – 29% Acetone**
- 2. Carrie Nail Polish Remover – 29% Acetone**

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 **LEBENZ ENTERPRISES** is engaged in the manufacture of galenicals and beauty products for personal use. It is duly registered with PDEA and handler of **P5C-00224001 and P3-00224001- Licenses dated 17 January 2012** as compounder and End-user of controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **LEBENZ ENTERPRISES** products

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

WHEREAS, after satisfying the requirements stipulated under the above mentioned regulations, **Lebenz Enterprises** products are 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**:

TO GRANT EXEMPTION and the issuance of a Certificate of Exemption, which shall be valid for one (1) year unless revoked, to **LEBENZ ENTERPRISES** products that contains controlled chemical below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d & f).

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

- (1) **The LEBENZ ENTERPRISES shall secure a license from PDEA and comply with the reporting requirements for the raw materials used in the manufacture of the products containing controlled chemicals 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 **LEBENZ ENTERPRISES** premises where the finished products are kept and/or used;
- (4) The **LEBENZ ENTERPRISES** 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 31st day of January, in the year of Our Lord, 2012 in Quezon City.

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

Attested:

(Sgd) **Undersecretary JORGE G. NECESITO**
Secretary of the Board