Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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# BOARD RESOLUTION NO. 247
**Series of 2013**

**SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF LIFELINE DIAGNOSTIC SUPPLIES, 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, LIFELINE DIAGNOSTICS SUPPLIES, INC.** with business addresses at #64 Web-Jet Bldg. Quezon Avenue, Quezon City, Philippines is seeking exemption from regulatory measures of the following products listed hereunder:

1. **MONOLISA HBc IgM PLUS with R10 Stopping Solution containing 2.5 – 10% Sulfuric Acid (H2SO4)**
2. **MONOLISA®Anti-HCV PLUS Version 2 (96 T & 480T) with R10 Stopping Solution containing 2.5 – 10% Sulfuric Acid (H2SO4)**

**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,** Immunoassay Drug test kits were granted exemption by the Board having Board Resolution No. 18, s. 2004 as an example. Considering that this type of reagents/products could not be extracted and contains no or miniscule amount of dangerous drugs/controlled chemicals, thus these products present no or negligible risk of abuse, necessary for medical or scientific purposes and for the interest of the public;

**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 **LIFELINE DIAGNOSTICS SUPPLIES, INC.** is a distributor and importer of In Vitro diagnostic kits with products containing controlled chemicals that are included in the kits that are used as a stopping solution. The company also distributes laboratory/life Science Supplies, Reagents and Instruments. It is duly registered with PEZA and handler of PDEA license **P5I-03413001-R017 dated 06 February 2013 and valid until 02 February 2014;**

**WHEREAS,** after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **LIFELINE DIAGNOSTICS SUPPLIES, INC'** products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(c, d, e & f);

**WHEREAS,** after satisfying the requirements stipulated under the above mentioned regulations**, LIFELINE DIAGNOSTICS SUPPLIES, INC' 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 Certificate of Exemption, which **shall be valid for one (1) year** unless revoked, **LIFELINE DIAGNOSTICS SUPPLIES, INC.** products that contains 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 **LIFELINE DIAGNOSTICS SUPPLIES, 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 LIFELINE DIAGNOSTICS SUPPLIES, INC.** premises where the finished products are kept and/or used;

   (4) The **LIFELINE DIAGNOSTICS SUPPLIES, 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 12th day of September, 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