



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD RESOLUTION NO. 136
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF ELIASAPH 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, **ELIASAPH INC.** with business address at Blk. 173 Lot 12, Mahogany St., Sitio Seville North Fairview, Quezon City, Philippines is seeking exemption from regulatory measures for the following products containing controlled chemicals, to wit:

1. **HAV IgM ELISA (IgM Antibody to Hepatitis A Virus ELISA Assay) – $\geq 1.5\%$ Sulfuric Acid**
2. **H.Pylori IgG Kit – $\geq 1-5\%$ Sulfuric Acid**
3. **H.Pylori IgM Kit – $\geq 1-5\%$ Sulfuric Acid**
4. **Measles IgG ELISA – $\geq 1-5\%$ Sulfuric Acid**
5. **Measles IgM ELISA – $\geq 1-5\%$ Sulfuric Acid**
6. **Mumps IgG ELISA – $\geq 1-5\%$ Sulfuric Acid**
7. **Mumps IgM ELISA – $\geq 1-5\%$ Sulfuric Acid**
8. **Salmonella Typhi IgG ELISA – $\geq 1-5\%$ Sulfuric Acid**
9. **Salmonella IgM ELISA – $\geq 1-5\%$ Sulfuric Acid**
10. **Chikungunya Virus IgM – $\geq 1-5\%$ Sulfuric Acid**
11. **Chikungunya Virus IgM u-capture with Stop Solution containing $\geq 1 - < 5\%$ Sulfuric 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, 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 **ELIASAPH INC.** started its business as family corporation focusing on the diagnostic market. It is concentrating mainly on the development and advancement of diagnostic reagents and instruments in the Philippines in respect to laboratory market requirements; an authorized distributor of Nova Tec Diagnostica Germany and Elisa test kits. The company is duly registered with PDEA and handler of **P5I-01325001 dated 02 November and valid until 02 November 2012**;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **ELIASAPH 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, **ELIASAPH INC’S product is 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, **ELIASAPH INC’S** product 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 ELIASAPH INC.** shall secure a license from the PDEA and comply with the reporting requirements for the raw materials used in the manufacture of the said product as provided for in Board Regulation No. 3, Series of 2003;
 - (2) The Board shall strictly monitor subject finished product from their manufacture/compounding to distribution to end-users;
 - (3) The DDB-PDEA Monitoring Team shall have free access to **ELIASAPH INC.** premises where the finished product is kept and/or used;
 - (4) The **ELIASAPH INC.** 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 18th day of October, in the year of Our Lord, 2012 in Quezon City.

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

Attested:

(Sgd.) **Assistant Secretary BENJAMIN P. REYES**
OIC-Secretary of the Board