Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 87
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF MERCK, INC. PHILIPPINES

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, MERCK, INC. PHILIPPINES with business address at 24/F GT Tower International, 6813 Ayala Ave., Cor. H.V. dela Costa St., Salcedo Village, Makati City, Philippines is seeking exemption from specific measures of regulatory control requirements to the following reagents/chemicals that contain controlled chemicals**;**

1. **DNA Staining Kit according to Feulgen 5 M Hydrochloric Acid - >10 -<20% HCL**
2. **Hydrochloric Acid Solution 5 mol/1 (5N) - >10 - <20% HCL**
3. **Hydrochloric Acid 6 mol/L.suitable for biopharmaceutical production EMPROVE ® bio - >1 -<20% HCL**
4. **Hydrochloric acid c(HCL) = 2 mol/1 (2N) Titripur ® - >=5% - < 10% HCL**
5. **Iron Standard 1000mg Fe, (FeCl3 in 15% HCL) Titrisol ® - >10 -<20% HCL**
6. **Antimony Standard Solution traceable to SRM from NIST Sb2O3 in HCL 2 mol/1 1000mg/1 Sb CertiPUR® - >=5% - < 10% HCL**
7. **Antimony ICP Standard traceable to SRM from NIST Sb2O3 in HCL 7% 1000mg/1 Sb CertiPUR® - >=5% - < 10% HCL**
8. **OSTEOMOLL ® rapid decalcifier-solution for Hisdtology - >10 -<20% HCL**
9. **Calcium Standard 1000mg Ca (CaCl2 in 6.5% HCL) Titrisol ® - >5% - < 10% HCL**
10. **Chromium Standard 1000mg Cr, (CrCl3 in 4.2% HCL) Titrisol ® - >=1% - < 5% HCL**
11. **Magnesium Standard 1000mg Mg, (MgCl2 in 6% HCL) Titrisol ® - >=5% - < 10% HCL**
12. **Chlorine test (low) in drinking water Refill pack for 1.14978.0001 (0.1-0.2 - 0.3 - 0.4-0.6 - 0.8 - 1.0 - 1.5 - 2.0 mg/1 Cl2 Microquant ® Reagenz 2, Cl2-2B - >15% - < 25% HCL**
13. **Sulfuric acid c(H2SO4) = 2.5 mol/1 (5N) TitriPUR ® - >15% - < 25% HCL**
14. **Sulfuric acid c(H2SO4) = 0.5 mol/1 (1N) TitriPUR ® - >1% - < 5% HCL**
15. **Sulfuric acid 25% for analysis EMSURE® - 25% H2SO4**

16. **Bilirubin Auto Total FS Reagent R1 as part of the kits: 1 0811xxxxxxx – 1 – 5% HCL**
17. **Bilirubin Auto Direct FS Reagent R2 as part of the kits: 1 0821xxxxxxx – 1 – 5% HCL**
18. **Urinary Calculi Analysis Reagent R12: Colour reagent solution – <2% Methyl Ethyl Ketone (MEK)**
19. **Phosphate FS Reagent R1 as part of the kits: 1 5211 xxxxxx - <2% 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 when the Table II chemical is a normal ingredient in consumer goods or finished products; 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, **Merck** started their Pharma operations in 1973 as a division of Zuellig Pharma Corp. In 1977, Merck spun off from Zuellig Pharma to form a separate company known as E. Merck Pharmaceuticals. The company organized its activities into three business sectors such as Pharmaceutical, Laboratory and Specialty Chemicals. The chemical sectors are engaged in the importation of finished forms and sales of locally selected chemical products consisting of reagents, diagnostics, pigments, fine chemicals, industrial chemicals and pharmaceutical raw materials. It is duly registered with PDEA and handler of Licenses **P5I-00782001-R036/P5DWI-00782001-R037 dated 14 March 2012 and valid until 09 March 2013** as importer/distributor and bulk depositor of controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **MERCK, INC. PHILPPINES** products that contain controlled chemicals, in accordance with the provisions of Section 4-2(d, e & f);

WHEREAS, after satisfying the requirements under the above mentioned regulations**, MERCK, INC. PHILPPINES 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:**

TO GRANT EXEMPTION and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to **MERCK, INC. PHILIPPINES** products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d):

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

(1) **That MERCK, INC. PHILIPPINES shall secure a license from 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 MERCK, INC. PHILIPPINES premises where the finished products are kept and/or used;

(4) That MERCK, INC. PHILIPPINES 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 23rd day of August , 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