



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

3/F, DDB – PDEA Building, NIA Road, National Government Center, East Triangle, Diliman, Quezon City, Philippines
P.O Box No. 3682 Manila, Tel. No. 929-1753, Telefax 929-1546, Website: www.ddb.gov.ph, E-mail: info@ddb.gov.ph

BOARD RESOLUTION NO. 100
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF EMPRESS DENTAL LABORATORIES 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, EMPRESS DENTAL LABORATORIES INC. with business address at 6/F NET 1 Center Building, 26th St. Cor., 3rd Avenue, Crescent Park, West Bonifacio, Taguig City, Philippines is seeking exemption from specific measures of regulatory control requirements on the following dental materials (**Branded and Generic**) containing controlled chemicals:

1. **Liquid for Ceramics – 2% Sulfuric Acid; 2.5 -10% Hydrochloric Acid**
2. **Paste for Ceramics/Opaque Materials – 2.5 Sulfuric Acid and 2.6% – 10% Hydrochloric Acid**
3. **Die Spacer/Thinner – 1-25% Methyl Ethyl ketone**
4. **Staining Materials for Ceramics – 2% Sulfuric Acid**
5. **Die Spacer/Liner – 5-10% Sulfuric Acid; 45-75% Methyl Ethyl ketone**
6. **Acrylic Liquid – 90% Butanone (MEK)**
7. **Adhesive Materials – 70% Acetone**
8. **Hardener (Bego Difpix/Kerr Lab Die Hardener)– 11- 20% Toluene**
9. **Separating Liquid – 2.5 – 10% Hydrochloric Acid**
10. **Hardener – 11-20% Toluene**
11. **Adhesive – 70% Acetone**
12. **Cleaning Liquid Green – 2.5 -10% Hydrochloric Acid**
13. **Bego Wiolyte – 5 -10% Sulfuric Acid**
14. **Gramm SG Flash (00310-0002) – 1.5% Sulfuric Acid**
15. **Gramm S-ACT (00310-0001) – 15% 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, 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 **EMPRESS DENTAL LABORATORIES INC.** is a German owned company engaged in the manufacture and export of dental prosthesis. They started its operation in September 1994 as a small scale enterprise. And later grow into a robust and well established organization. The company produces dental prosthesis products inclusive of ceramic Crowns and Bridges, Full cast Crowns, implants. Chrome cobalt plates, dentures, IPS crowns, telescopic crowns and bridges, attachments, implants, zirconia and others. The company is duly PDEA registered and handler of **P5IM-02910001-R024 dated 20 July 2012**. Such license authorized to import, as end-user of controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **Empress Dental Laboratories Inc.** finished products that contain controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d, e & f);

WHEREAS, Section 4(2-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 Board is satisfied that the mixture is formulated in such a way that the controlled chemical or chemicals cannot be easily extracted or recovered for the illicit manufacture of dangerous drugs and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered or extracted;

WHEREAS, after satisfying the requirements under the above mentioned regulations, **Empress Dental Laboratories Inc.** products are no longer covered by the provisions of Section 10 (Application for import, export or transit permits), and Section 11 (Grant of import, export or transit permits), of BR No.3, S. 2003.

WHEREAS, the Technical Working Group deliberated and recommended to the Board, issuance of appropriate **Certificate of Exemption** to **EMPRESS DENTAL LABORATORIES INC.** request for exemption from specific measures of regulatory control requirements for the above-mentioned imported finished products and as such, subject certification shall be valid for one (1) year unless revoked;

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED**:

- a. **TO GRANT EXEMPTION** and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to the following **EMPRESS DENTAL LABORATORIES, INC.’** dental materials (**Branded and Generic**) that contain controlled chemicals below and above the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(f):
- b. That the above cited exemption shall still be subject to the following conditions:
 - (1) That **EMPRESS DENTAL LABORATORIES, INC.** shall comply with the reporting requirements as provided for in Board Regulation No. 3, Series of 2003;

- (2) The Board shall strictly monitor subject products/chemicals from their importation to end-user;
- (3) The DDB-PDEA Monitoring Team shall have free access to **EMPRESS DENTAL LABORATORIES INC.** premises where the products/chemicals are kept and/or used;
- (4) That **EMPRESS DENTAL LABORATORIES 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 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