



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. 12
Series of 2013

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF ATOMED CEBU 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, ATOMED CEBU INC with business address at MEPZ II, Basak, Lapu Lapu City, Philippines is seeking exemption from specific measures of regulatory control requirements to the following reagents/chemicals that contain controlled chemicals:

- 1. ACRISIA UB PRIMER HARDENER – 27.2% Toluene**
- 2. ACRISIA UB PRIMER WHITE – 29.7% Toluene**
- 3. ELECTRONE TYPE-5 ATOM WHITE 009 – 7.6% Toluene**
- 4. ELECTRONE TYPE-5 ATOM CLEAR – 19.6% Toluen**
- 5. ELECTRONE TYPE-5 ATOM GREEN 004 – 8.4% Toluen**
- 6. ELECTRONE TYPE-5 HARDENER – 19.8% Toluene**

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, ATOMED CEBU INC. is duly registered with PEZA and is engaged in the manufacture of medical devices and equipment for infants and children care like of the incubator parts that are currently on trial production. It is duly registered with PDEA and handler of Licenses **P5IM-00596001-R034-H/P6-00596001-R031H and valid until 02 February 2013** as importer/distributor of controlled chemicals;

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

Bd. Res. on Granting exemption from specific measures of regulatory control requirements to 1
certain finished products of Atomed Cebu Inc.

WHEREAS, after satisfying the requirements under the above mentioned regulations, **ATOMED CEBU 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, during the Caucus of the Board held on 12 December 2012, the matter was presented and was eventually unanimously approved in principle by those in attendance, subject to confirmation by the Board at its next regular meeting;

WHEREAS, in order to facilitate its confirmation, the said matter, along with the other concerns approved in principle during the Caucus, was subjected to an Ad Referendum, which was thereafter signed by at least nine (9) Members of the Board constituting a quorum on January 16, 2013.

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED, GRANTING EXEMPTION** and the issuance of a Board Resolution for Exemption, which shall be valid for one (1) year unless revoked, to **ATOMED CEBU INC.** products containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the following provisions of Section 4-2(d):

- a. That the above cited exemptions shall still be subject to the following conditions:
 - (1) **That ATOMED CEBU INC. 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 **ATOMED CEBU INC.** premises where the finished products are kept and/or used;
 - (4) That **ATOMED CEBU 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 16th day of January, in the year of Our Lord, 2013 in Quezon City.

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

Attested:

(Sgd) **Assistant Secretary AMADOR S. PABUSTAN**
OIC-Secretary of the Board