Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD
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BOARD RESOLUTION NO. 108
Series of 2012

SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCTS OF ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division

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, ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division. with business address at 102 EDSA, Mandaluyong City, Philippines is seeking exemption from specific measures of regulatory control requirements to the following reagents/products containing controlled dangerous drugs/ chemicals listed hereunder:

1. **MULTIGENT Opiates (Morphine, Benzodiazepines, Methamphetamine, Methadone, Nitrazepam, Phencyclidine, Propoxyphene, Secobarbital)**
2. **MULTIGENT Methadone**
3. **MULTIGENT Amphetamine/Methamphetamine Reagent**
4. **MULTIGENT Barbiturates**
5. **MULTIGENT Benzodiazepines**
6. **MULTIGENT Cocaine Reagents**
7. **MULTIGENT Cannabinoids CAL 20, 50,100, 200**
8. **MULTIGENT Ecstasy**
9. **MULTIGENT Phencyclidine**
10. **MULTIGENT Propoxyphene**
11. **MULTIGENT Serum Benzodiazepines**
12. **MULTIGENT DOA MC**
13. **MULTIGENT DOA MC**
14. **MULTIGENT DOA MC**
15. **MULTIGENT DOA MC**
16. **MULTIGENT DOA MC**
17. **MULTIGENT Opiates 150 CAL**
18. **MULTIGENT Opiates 300 CAL**
19. **MULTIGENT Opiates 500 CAL**
20. **MULTIGENT Opiates 1000 CAL**
21. **MULTIGENT DOA MC 1 Control Sets (1&2)**
22. **Phenobarbital Abbott Clinical Chemistry**
23. **AxSYM Amphetamine/Methamphetamine II Reagent**
24. **AxSYM Barbiturates II Reagents**
25. **AxSYM Benzodiazepines**

26. **AxSYM Cannabinoids**
27. **AxSYM Cocaine**
28. **AxSYM Methadone**
29. **AxSYM Opiates**
30. **AxSYM Phenobarbital**
31. **AxSYM Phencyclidine II Reagents**
32. **XSYSTEMS Amphetamine/Methamphetamine II Calibrators**
33. **XSYSTEMS Barbiturates Calibrators II U (A, B-F)**
34. **XSYSTEMS Benzodiazepines Calibrators (A, B-F)**
35. **XSYSTEMS Cannabinoids Calibrators (A,B,C,D,E,F)**
36. **XSYSTEMS Cocaine Calibrators (Metabolite, A, BF)**
37. **XSYSTEMS Methadone Calibrators (A,B,C,D,E,F)**
38. **XSYSTEMS Opiates (A,B,C,D,E,F)**
39. **XSYSTEMS Phencyclidine Calibrators (A, B-F)**

WHEREAS, this matter was brought to the attention of the Board by importers affected by the said requirement under Board Regulation No. 3, arguing that the importation of drug test kits should be exempted from the coverage of Sec. 5, Art III of the said regulation because these kits do not contain any dangerous drugs and that if ever there are, these are so miniscule and the dangerous drugs therein cannot be readily extracted/recovered from it and if ever dangerous drugs could be extracted, it will not present a risk of abuse;

WHEREAS, Section 5, par (b), Article III of Board Regulation No. 3, among others, provides that for every importation of dangerous drugs and controlled chemicals or their preparation, the operator/importer must first have an import permit duly issued by PDEA prior to such importation;

WHEREAS, by virtue of this Board Regulation, one of the requirements being asked by the Bureau of Customs before releasing these kind of imported Drug Test Kits is the import permit being issued by PDEA;

WHEREAS, Section 5, par 2-a of Article II of the same Regulation also provides that the Board may exempt from specific measures of regulatory control requirements any preparation containing dangerous drugs when the Board is satisfied that:

a. The preparation is compounded in such a way as to present no or negligible risk of abuse;
b. The preparation does not contain more than one dangerous drug;
c. The dangerous drugs cannot be readily recovered from it in a quantity liable to present such a ;
d. The exemption is necessary for a medical or scientific purpose and is otherwise in the public interest;
e. The dangerous drug preparation is listed as an exempt preparation in the schedules annexed to the 1961 Single Convention on Narcotic Drugs, as amended.

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 **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics**

Division was founded since 1888 by Dr. Wallace C. Abbott, a Chicago physician. It a global, diversified healthcare company devoted to discovery, development, manufacture and marketing of pharmaceutical, and nutritionals products for children and adults. The company is a handler of **S5I-03353001-N008 issued on 05 December 2011 and valid until 12 December 2012** as importer of dangerous drugs and preparations containing Table 1 Controlled chemicals;

WHEREAS, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** products based on the following findings:

a. Extraction of dangerous drugs from membrane-type immunoassay test kits is difficult, impractical and uneconomical and does not present a risk of abuse. Furthermore, drug test kits are being used for medical and scientific purposes and therefore satisfy the criteria stated in sec 4 (2) of Board regulation No. 3, s. 2003. Thus, these membrane-type immunoassay drug test kits may be exempted from specific regulatory control requirements.

b. As such, the drug test kits from **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** are recommended to be exempted from some regulatory requirements provided by Board Regulation No. 3, s. 2003 stated in Section 4.

WHEREAS, be it **RESOLVED** as it is hereby **RESOLVED**, that the recommendation of the Technical Working Group (TWG) be **ADOPTED AND APPROVED** and that membrane-type immunoassay drug test kits (card and plastic) be as it is hereby, **EXEMPTED** from some specific regulatory control requirements under the Board Regulation No. 3, s. 2003, relative to their importation;

WHEREAS, after satisfying the requirements under the above mentioned regulations, **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division 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;**

WHEREAS, it has been determined by the DDB Technical Working Group (TWG) that **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** finished products containing dangerous drugs, in accordance with the provisions of Section 4-2(a &b).

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

a. **TO GRANT EXEMPTION** and the issuance of a Board Resolution on Exemption, which **shall be valid for one (1) year** unless revoked, to **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division'** finished products that contain dangerous drugs, in accordance with the provisions of Section 4-2).

b. That the above cited exemption shall still be subject to the following conditions:

(1) That **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** 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 products/chemicals from their importation to end-user;

(3) The DDB-PDEA Monitoring Team shall have free access to **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division**' premises where the products/chemicals are kept and/or used;

(4) That **ABBOTT LABORATORIES-Diagnostic Division Abbott Diagnostics Division** 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