REPUBLIC OF THE PHILIPPINES
OFFICE OF THE PRESIDENT
DANGEROUS DRUGS BOARD

BOARD REGULATION NO. 3
Series of 2020

SUBJECT: PLACING DRUG PRODUCTS CONTAINING CANNABIDIOL (CBD) WITH NO MORE THAN 0.1 PERCENT TETRAHYDROCANNABINOL IN SCHEDULE 4 OF THE PHILIPPINE SCHEDULE

WHEREAS, Republic Act No. 9165, or the Comprehensive Dangerous Drugs Act of 2002, as amended (the "Act"), provides that the Dangerous Drugs Board (the "Board") shall be the policy-making and strategy-formulating body in the planning and formulation of policies and programs on drug prevention and control;

WHEREAS, Section 93 of the Act provides that the Board shall have the power to Reclassify, Add or Remove Any Drug from the List of Dangerous Drugs;

WHEREAS, "extracts and tinctures of cannabis," which includes cannabidiol, are listed under Schedule I while "cannabis and cannabis resin" are listed in Schedules I and IV of the 1961 United Nations Single Convention on Narcotic Drugs as amended by the 1972 Protocol (the "1961 UN Convention");

WHEREAS, tetrahydrocannabinol is listed in Schedule 1 while delta-9-tetrahydrocannabinol is listed in Schedule II of the 1971 United Nations Single Convention on Psychotropic Substances (the "1971 UN Convention");

WHEREAS, the United States Drug Enforcement Administration has issued an order placing Food and Drug Administration-approved drugs that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in Schedule V of the United States Controlled Substances Act;

WHEREAS, the United States Food and Drug Administration approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome;

WHEREAS, the European Commission and the European Medicines Agency have also approved the marketing authorization for the same drug which allows its distribution throughout Europe;

WHEREAS, the Act states that the government shall aim to achieve a balance in the national drug control program so that people with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications, which include the use of dangerous drugs.

Section 1. Definition of Terms

a. Cannabidiol (CBD) – one of the naturally occurring cannabinoids found in cannabis plants.

b. Drug Product – refers to products which are in finished pharmaceutical dosage form that contain dangerous drugs that may or may not be in association with other active or inactive ingredients.

c. Schedule 1 – a category of dangerous drugs in the Philippine Schedule with no currently accepted medical use in the Philippines and with lack of accepted safety for use of such dangerous drugs under medical supervision. Schedule 1 substances are subject to measures of control provided for Schedule IV substances in the 1961 United Nations Single Convention on Narcotic Drugs and Schedule I substances in the 1971 Convention on Psychotropic Substances.

d. Schedule 2 – a category of dangerous drugs in the Philippine Schedule which may have currently accepted medical use in the Philippines but with high potential for abuse that may lead to severe psychological or physical dependence. Schedule 2 substances are subject to measures of control provided for Schedules I and II substances in the 1961 United Nations Single Convention on Narcotic Drugs and Schedule II substances in the 1971 Convention on Psychotropic Substances.

e. Schedule 3 – a category of dangerous drugs under the Philippine Schedule with currently accepted medical use in treatment in the Philippines; has a potential for abuse less than the drug in Schedules 1 and 2 that may lead to moderate or low physical dependence or high psychological dependence.

f. Schedule 4 – a category of dangerous drugs in the Philippine Schedule with currently accepted medical use in the Philippines and with lesser potential for abuse than Schedule 3 dangerous drugs that may lead to limited physical or psychological dependence. Schedule 4 substances are subject to measures of control provided for Schedule III substances in the 1961 United Nations Single Convention on Narcotic Drugs and Schedule IV substances in the 1971 Convention on Psychotropic Substances.

Section 2. Reclassification

Drug products containing CBD with no more than 0.1 percent (0.1%) tetrahydrocannabinol (“*Drug Products Containing CBD*” for brevity) are hereby reclassified from Schedules 1 and 2 to Schedule 4 of the Philippine Schedule.

Section 3. Physicians Authorized to Prescribe Drug Products Containing CBD

Only physicians with S2 Licenses are members of specialty divisions or societies engaged in neurology can prescribe drug products containing CBD.

Section 4. Use of Special Prescription Form for Dangerous Drugs

Physicians shall use the Special Prescription Form for Dangerous Drugs of the Department of Health in prescribing drug products containing CBD.

Section 5. Authorization from the Dangerous Drugs Board

An Authorization from the Dangerous Drugs Board shall be secured prior to or simultaneous with the submission of an application to avail of Drug Products Containing CBD through the Compassionate Special Permit for Restricted Use of Dangerous Drugs with the Food and Drug Administration.

The application for Authorization shall be addressed to the Executive Director of the Dangerous Drugs Board, thru the Legal Affairs Division, together with the following information/requirements:

a. Contact details of the patient or authorized representative;
b. Patient profile or clinical chart of the patient;
c. Special Prescription Form for Dangerous Drugs from an S2-licensed physician indicating the drug product containing CBD with no more than 0.1% tetrahydrocannabinol;
d. Payment of Five Hundred Pesos (Php 500.00) fee.

Section 6. Control Requirements

All distributors, importers, manufacturers, and retailers of Drug Products Containing CBD shall comply with regulatory requirements set forth in Regulation No. 1, Series of 2014 and other relevant Regulations.

Section 7. Sanctions

Any person found to be in violation of this Regulation shall be dealt with pursuant to the Act.

Section 8. Separability Clause

In the event any of the provisions in this Regulation is declared invalid, the remaining provisions shall continue to be in full force and effect.

Section 9. Effectivity

This Regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation and registration with the Office of the National Administrative Register (ONAR), UP Law Center, Quezon City.

APPROVED and **ADOPTED** this 24th day of _____, in the year of Our Lord, 2020 in Quezon City.

Secretary CATALINO S. CUY, CEO VI
Chairman, Dangerous Drugs Board

Attested:

Undersecretary EARL P. SAAVEDRA, CESE
Secretary of the Board