



REPUBLIC OF THE PHILIPPINES  
OFFICE OF THE PRESIDENT

**DANGEROUS DRUGS BOARD**

**BOARD RESOLUTION NO. 1  
Series of 2020**

**SUBJECT: ON THE PRODUCT REGISTRATION OF LIANHUA QINGWEN  
CAPSULES WITH THE FOOD AND DRUG ADMINISTRATION**

**Whereas**, Section 81 of the Comprehensive Dangerous Drugs Act of 2002, as amended (the “Act”), mandates the Dangerous Drugs Board (the “Board”) to formulate guidelines, in coordination with other government agencies, relative to transactions involving dangerous drugs and controlled precursors and essential chemicals, which may include the importation, distribution, sale, prescription, and dispensing thereof;

**Whereas**, the Board issued Regulation No. 1, Series of 2014 in compliance with the legal directive stated in the immediately preceding paragraph;

**Whereas**, the Food and Drug Administration received a product registration application from the Philippine Archipelago International Trading Corporation regarding *Lianhua Qingwen* capsules which contain 85 milligrams *Ephedrae Herba* per capsule;

**Whereas**, Ephedra is a plant-based substance used in traditional Chinese medicine to treat various lung problems. It contains Ephedrine, a Table I Substance in the 1988 United Nations Convention Against Illicit Traffic of Narcotic Drugs and Psychotropic Substances which forms part of the Annex to the Act;

**Whereas**, Ephedrine is classified as a dangerous drug pursuant to Regulation No. 4, Series of 2005 issued by the Board; Regulation No. 3, Series of 2019 also states that all plants containing substances listed in the 1961 Single Convention on Narcotic Drugs, the 1971 Single Convention on Psychotropic Substance, and *those classified by the Board as dangerous drugs, or are found to be sources thereof*, are classified as dangerous drugs;

**Whereas**, given the aforesaid issuances of the Board, Ephedra is considered as a dangerous drug in this jurisdiction;

**Whereas**, *Lianhua Qingwen*, originally used to treat influenza during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, is one of the recommended drugs in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia by the National Health Commission of China and the State Administration of Traditional Medicine of China;

**Whereas**, *Lianhua Qingwen* has been registered in Hong Kong, Macau, Thailand, and Brazil as “plant medicine,” food supplement, and/or natural health product, and has obtained marketing authorization in said countries;

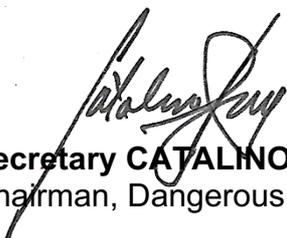
**Whereas**, reports have indicated that the Chinese Foreign Ministry has purchased 700,000 boxes of *Lianhua Qingwen* for distribution to all Chinese embassies; Health packages for Chinese students have also included said medicine;

**Whereas**, Section 2 of the Act provides 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;

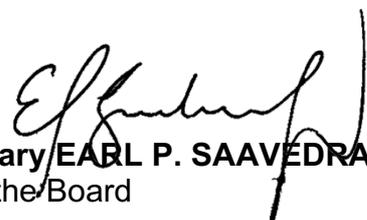
**Whereas**, given the current state of calamity and public health emergency brought about by the Coronavirus-2019, the Board is of the opinion that medicines which may include components listed as dangerous drugs, should be properly evaluated and considered, and that they comply with requirements set forth in the Act and relevant Regulations issued by the Board.

**NOW THEREFORE**, be it **RESOLVED**, as it is hereby **RESOLVED**, that the Board interpose no objection to the product registration of *Lianhua Qingwen* capsules with the Food and Drug Administration (FDA); **PROVIDED**, that should FDA issue a Certificate of Product Registration, the importer thereof shall secure the proper License from the Philippine Drug Enforcement Agency and comply with all regulatory requirements set forth in Regulation No. 1, Series of 2014 and other relevant issuances of the Board.

**APPROVED** and **ADOPTED** this 5<sup>th</sup> day of May, in the year of our Lord, 2020, in Quezon City.

  
**Secretary CATALINO S. CUY**  
Chairman, Dangerous Drugs Board

Attested:

  
**Undersecretary EARL P. SAAVEDRA**  
Secretary of the Board