

Submitted electronically via www.regulations.gov

March 14, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rom 1061
Rockville, MD 20852

Re: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Dronabinol (*delta-9-tetrahydrocannabinol*) and its Stereoisomers; Cannabis, Cannabis Resin, Extracts and Tinctures; Cannabidiol Preparations; and Pharmaceutical Preparations of Cannabis; Request for Comments. Docket No. FDA-2019-N-0767

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to provide comments on the notice International Drug Scheduling: Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Dronabinol (*delta-9-tetrahydrocannabinol*) and its Stereoisomers; Cannabis, Cannabis Resin, Extracts and Tinctures; Cannabidiol Preparations; and Pharmaceutical Preparations of Cannabis. Founded in 1881, CHPA is the national trade association representing the manufacturers of over-the-counter drugs and dietary supplements in the United States. As knowledge of the potential therapeutic effects of cannabidiol (CBD), one of the many compounds derived from the cannabis plant, evolves, OTC drug and dietary supplement manufacturers may look at ways to develop safe and effective CBD treatments for consumers and therefore have an interest in this notice.

CHPA has reviewed the findings of the forty-first meeting of the World Health Organization Expert Committee on Drug Dependence (Committee) as submitted to the Secretary-General of the United Nations and set forth in the Federal Register notice in regards to cannabis and cannabis resin and cannabidiol preparations. CHPA agrees with the Committee's recommendations, specifically with regards to the following:

1. Delete cannabis and cannabis resin from Schedule IV of the 1961 Convention; and
2. Add a footnote to the entry for cannabis and cannabis resin in Schedule I of the 1961 convention to read, "*Preparations containing predominately cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol are not under international control.*"

We would note that 0.2 percent delta-9-tetrahydrocannabinol concentration proposed by the Committee differs from the 0.3 percent allowable under United States federal law, pursuant to the recent enactment of the Agricultural Improvement Act of 2018.

CHPA would therefore urge the United States Secretary of Health and Human Services to recommend the United States Secretary of State agree with the findings of the Committee and urge the adoption of the suggested changes.

Sincerely,

A handwritten signature in cursive script that reads "Carolyn Herrmann".

Carolyn Herrmann
Deputy General Counsel