

**BEFORE
THE UNITED STATES OF AMERICA
FOOD AND DRUG ADMINISTRATION**

**COMMENTS OF THE
AMERICAN HERBAL PRODUCTS ASSOCIATION
ON THE**

FDA's Request for Comments on International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; Cannabidiol; Request for Comments

April 23, 2018

The American Herbal Products Association (“AHPA”) is the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products.

On April 9, 2018 the Food and Drug Administration (“FDA”) published a request for information in the Federal Register (“the April 9 Notice”)¹ in which the agency solicited information and comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of five drug substances - Cannabis Plant and Resin; Extracts and Tinctures of Cannabis; Delta-9-Tetrahydrocannabinol; Stereoisomers of Tetrahydrocannabinol; and Cannabidiol. The April 9 Notice further details that “these comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs.” This FDA request for comment is in preparation for the WHO’s 40th Expert Committee on Drug Dependence (ECDD) which will take place in Geneva, Switzerland June 4-8, 2018.

AHPA’s members are engaged in the commerce of herbs and herbal products. In the course of this commerce many plant species are traded as bulk commodities, as plant extracts and finished products such as teas and dietary supplements, or as ingredients in such extracts and products, and may include cultivars of *Cannabis sativa* (including those that are classified as industrial hemp²). AHPA’s members therefore have an interest in the subject of the April 9 Notice described here insofar as that notice relates to this plant species and various products derived from it that are legal under federal law as excluded from the definition of “marihuana,”³ or are legal under State law in a State that allows such products to be cultivated, processed, sold, possessed and used.

¹ 83 Fed. Reg. 15155-15157.

² Section 7606 of the Farm Bill of 2013 defines industrial hemp to mean “the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

³ 21 U.S.C. § 802 (16).

These comments are therefore submitted on behalf of AHPA's members and consist of comments requested in the April 9 Notice related only to cannabidiol (hereinafter cannabidiol or CBD). AHPA has no comments on the other four substances specified in the April 9 Notice at this time.

Comments on the International Drug Scheduling of Cannabidiol (CBD)

AHPA supports the conclusions of the WHO 39th Expert Committee on Drug Dependence (ECDD) in November 2017,⁴ during which a pre-review of the international drug scheduling status of cannabidiol was performed and recommends that the United States also communicate agreement with these conclusions.

ECDD noted in its recommendations from the November 2017 pre-review that CBD is not currently a scheduled substance in its own right (only as a component of cannabis extracts). ECDD also found that no case reports of abuse or dependence relating to the use of CBD were identified, and that current information does not justify a change in this scheduling status nor does it justify scheduling of the substance.

AHPA supports the ECDD's conclusion that CBD requires no international drug scheduling as an individual substance and recommends and requests that the United States also express support for this position.

AHPA notes that the record of the ECDD's November 2017 meeting also reports that the pre-review of cannabis extracts and tinctures will take place at the fortieth ECDD meeting in May 2018, and recommended that extracts or preparations containing almost exclusively CBD be subject to critical review at that upcoming meeting. AHPA is aware of no information that suggests that extracts or preparations of *Cannabis* containing almost exclusively CBD are any more subject to abuse or dependence than CBD itself and therefore recommends and requests that the United States support a position to acknowledge that such extracts and preparations should not be scheduled under any international drug control convention to which the United States is a party.

⁴ As recorded in: WHO Expert Committee on Drug Dependence, Thirty-ninth Report, 2018.

AHPA appreciates the opportunity to provide these comments for consideration as the Food and Drug Administration prepares for the 40th Expert Committee on Drug Dependence (ECDD).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael McGuffin". The signature is fluid and cursive, with the first name "Michael" being more prominent than the last name "McGuffin".

Michael McGuffin
President, American Herbal Products Association
8630 Fenton St., #918
Silver Spring, MD 20910
(301) 588-1171 x201
mmcguffin@ahpa.org