FDA STATEMENT

FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward

For Immediate Release:

January 26, 2023

Statement From:

Janet Woodcock, M.D.
Principal Deputy Commissioner - Office of the Commissioner

Español (https://www.fda.gov/news-events/press-announcements/la-fda-concluye-que-los-marcos-regulatorios-existentes-para-alimentos-y-suplementos-no-son)

Given the growing cannabidiol (CBD) products market, the U.S. Food and Drug Administration convened a high-level internal working group to explore potential regulatory pathways for CBD products. Today we are announcing that after careful review, the FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The agency is prepared to work with Congress on this matter. Today, we are also denying three citizen petitions that had asked the agency to conduct rulemaking to allow the marketing of CBD products as dietary supplements.

The use of CBD raises various safety concerns, especially with long-term use. Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system. CBD exposure is also concerning when it comes to certain vulnerable populations such as children and those who are pregnant.

A new regulatory pathway would benefit consumers by providing safeguards and oversight to manage and minimize risks related to CBD products. Some risk management tools could include clear labels, prevention of contaminants, CBD content limits, and measures, such as minimum purchase age, to mitigate the risk of ingestion by children. In addition, a new pathway could provide access and oversight for certain CBD-containing products for animals.

The FDA's existing foods and dietary supplement authorities provide only limited tools for managing many of the risks associated with CBD products. Under the law, any substance, including CBD, must meet specific safety standards to be lawfully marketed as a dietary supplement or food additive.

The working group, which I chair, has closely examined studies related to the CBD-based drug Epidiolex (https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms), published scientific literature (https://www.fda.gov/media/152317/download), information submitted to a public docket (https://www.regulations.gov/docket/FDA-2019-N-1482), as well as studies both conducted and commissioned by the agency. Given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives. For example, we have not found adequate evidence to determine how much CBD can be consumed, and for how long, before causing harm. Therefore, we do not intend to pursue rulemaking allowing the use of CBD in dietary supplements or conventional foods.

CBD also poses risks to animals, and people could be unknowingly exposed to CBD through meat, milk and eggs from animals fed CBD. Because it is not apparent how CBD products could meet the safety standard for substances in animal food, we also do not intend to pursue rulemaking allowing the use of CBD in animal food. A new regulatory pathway could provide access and oversight for certain CBD-containing products for animals.

The FDA will continue to take action against CBD and other cannabis-derived products to protect the public, in coordination with state regulatory partners, when appropriate. We will remain diligent in monitoring the marketplace, identifying products that pose risks and acting within our authorities. The FDA looks forward to working with Congress to develop a cross-agency strategy for the regulation of these products to protect the public's health and safety.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Inquiries

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888-INFO-FDA

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U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

February 13, 2023

Mr. Rod Kight
Kight Law Office PC
P.O. Box 526
Edneyville, North Carolina 28787

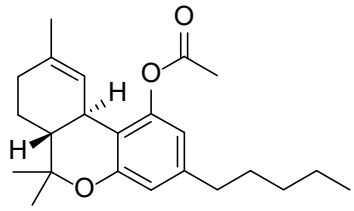
Dear Mr. Kight:

This is in response to your letter dated August 17, 2022 and subsequent email dated February 7, 2023, in which you request the control status under the Controlled Substances Act (CSA) of THC acetate ester (THCO). The only substances of which the Drug Enforcement Administration (DEA) is aware of the THC acetate ester are delta-9-THCO (delta-9-THC acetate ester) and delta-8-THCO (delta-8-THC acetate ester). The Drug Enforcement Administration (DEA) reviewed the CSA and its implementing regulations with regard to the control status of these substances.

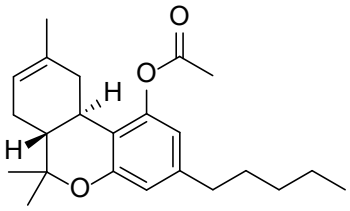
The CSA classifies tetrahydrocannabinols (THC) as controlled in schedule I. 21 U.S.C. § 812, Schedule I(c)(17); 21 CFR 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term "tetrahydrocannabinols" means those "naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant." 21 CFR § 1308.11(d)(31).

Delta-9-THCO and delta-8-THCO do not occur naturally in the cannabis plant and can only be obtained synthetically, and therefore do not fall under the definition of hemp. Delta-9-THCO and delta-8-THCO are tetrahydrocannabinols having similar chemical structures and pharmacological activities to those contained in the cannabis plant. Thus, delta-9-THCO and delta-8-THCO meet the definition of "tetrahydrocannabinols," and they (and products containing delta-9-THCO and delta-8-THCO) are controlled in schedule I by 21 U.S.C. § 812(c) Schedule I, and 21 CFR § 1308.11(d). The Controlled Substances Code Number (CSCN) assigned to these substances are 7370, which is that of tetrahydrocannabinols, and the conversion factors (CF) are 1.00. Because delta-9-THCO and delta-8-THCO are controlled substances, they do not meet the definition of controlled substance analogues under 21 U.S.C. § 813.

The chemical structures shown below were used to make these determinations. If you have any further questions, please contact the Drug and Chemical Evaluation Section at DPE@dea.gov or (571) 362-3249.



delta-9-THCO (delta-9-THC acetate ester)
schedule I
CSCN 7370
CF 1.0



delta-8-THCO (delta-8-THC acetate ester)
schedule I
CSCN 7370
CF 1.0

Sincerely,

Terrence L. Boos, Ph.D., Chief
Drug & Chemical Evaluation Section
Diversion Control Division

Cc: Charlotte District Office

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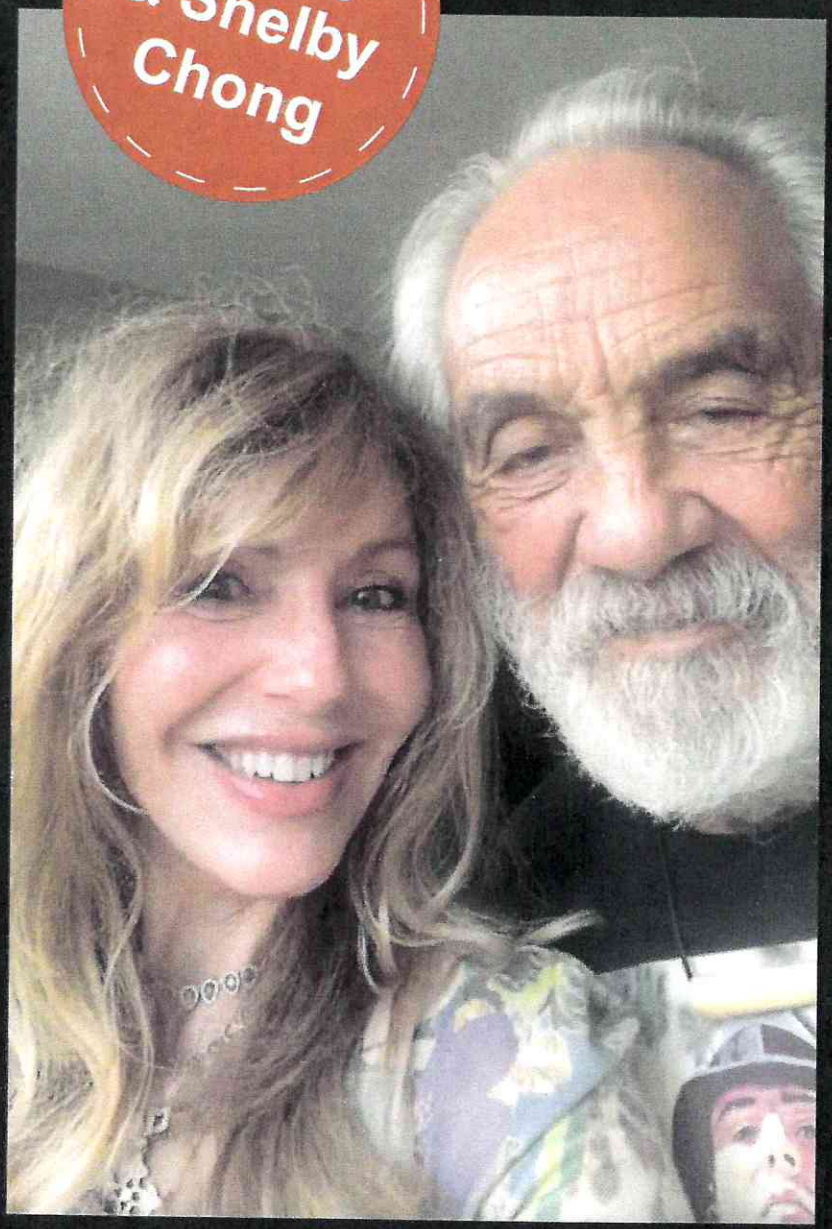


[redacted]

at

[redacted]

CBD | HEMP | THC-O
HHC | LEGAL D9

[redacted], ND

[redacted] is an 18+ establishment with ID verification. All hemp and CBD products contain less than .3% Delta 9 THC per the 2018 Farm Bill.

Redeem this coupon for a **Free Sample*&**

50% OFF**

YOUR PURCHASE OF ANY HEMP, CBD, OR CANNABINOID PRODUCT

*Gummy, Preroll, or Salve.
**Limit 1 item, cannot be combined with any other coupon or reward.

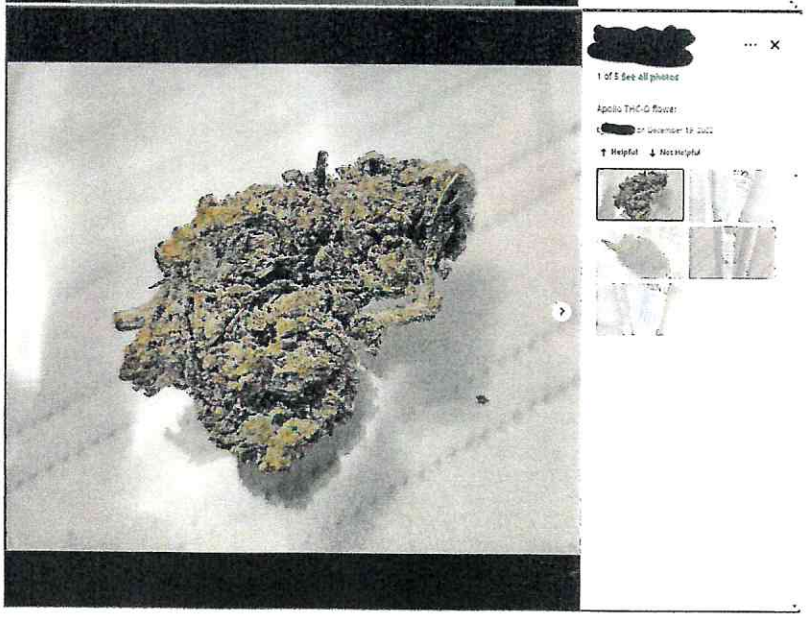
[redacted] ND

12/19/2022

5 photos

Amazing selection of products. Only smoke shop in town with n2o as far as i know. They have a decent selection of legal hemp products as well; their THC-O flower is good quality. Largest selection of glass in town as well as far as i know.



May 29, 2022 ·

Sunday Funday! Come in and pick out your favorite pre roll for this perfect day!

[redacted]
June 6, 2022 ·

Hello hemp friends! 😊 If you didn't know already we have HHC tinctures! We have these in 1,500 milligram's and 3,000 milligram's.😊 Have a great week, stop by and make it better😊. We close at 9p.m. tonight!

#cbdbenefits #tincture #HHC
[redacted]#cbd


$39.99
30MG PER SERVING
300MG THC-O
10-30MG THC-O GUMMIES

[redacted] June 28, 2022 ·

"D6 is not legal in North Dakota and thusly not available [redacted]

3

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1:34 PM
1/3/2023