DRUG ENFORCEMENT ADMINISTRATION

Status and Trends Update

Drug & Chemical Evaluation Section

DPE@dea.gov

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DISCLAIMER

Diversion Control Division

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Diversion Control Division

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About the Section

- Part of Diversion Operations
- Consists of three Units
  - Drug & Chemical Control Unit
  - Data Analysis Unit
  - Schedule I Researcher and International Control Unit
- Section consists of senior scientists: chemists, pharmacologists, drug science specialists, toxicologist, epidemiologist, and statistician

Overview

Activities:

- Scientific evaluations pertaining to drug control and chemical regulations under Controlled Substances Act (CSA)
  - Control status determinations
  - Drug scheduling; chemical controls
  - Exemptions
  - Schedule I researcher registration
- Generate reports regarding drug abuse, chemical diversion, and emergent/changing drug trafficking trends
- Provide technical and regulatory control information, trends, and support to federal, state, and local public health and law enforcement officials
- Special programs to inform regulatory decisions and strategies

Is the Substance Scheduled / Listed?

- Find it on e-CFR, 21 §CFR 1308
- Find it in DEA Orange Book
- Email DPE@DEA.GOV

Online: eCFR

- https://www.ecfr.gov/current/title-21/chapter-II
- **Available all time, any time**
- **Updated as New Control Action Effective**
- **Links to Public Laws, Federal Registers**

Orange Boo

U.S. Department of Justice
Drug Enforcement Administration
Diversion Control Division
Drug and Chemical Evaluation Section

LISTS OF:
CONTROLLED SUBSTANCES
SCHEDULING ACTIONS
REGULATED CHEMICALS

APRIL 2022

THESE LISTS ARE ROUTINELY UPDATED THROUGHOUT THE CALENDER YEAR
PLEASE VISIT HTTPS://WWW.DEADIVERSION.USDOJ.GOV/SCHEDULES/ORANGEBOOK/ORANGEBOOK.PDF
FOR THE MOST CURRENT VERSION OF THIS PUBLICATION.

Diversion Control Division

Controlled Subs

istration.Help@dea.gov | 1.800.882.9539

RCES CONTACT US

HOME > RESOURCES
> CONTROLLED SUBSTANCE SCHEDULES

Listed Chemicas

Scheduling Action

Alphabetical Order

Chronological Orde

l and II Regulated Chemicals

habetical Order

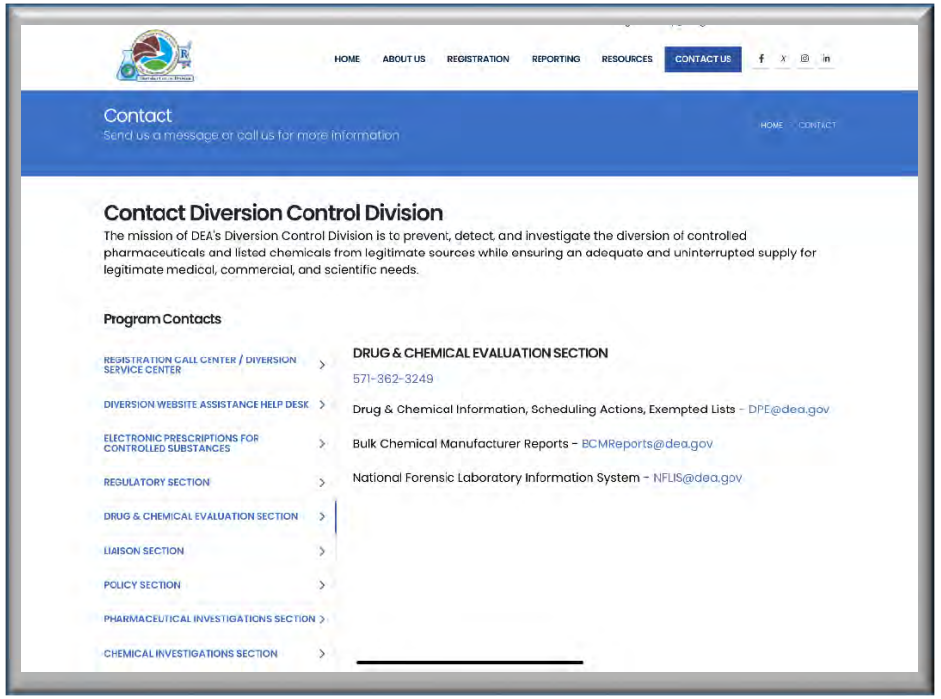
Chemical Code Number

Number

t Uses and Threshold Quantities

Control Status Inquiries

- **At anytime write into DEA or email the control status of a substance or chemcial**
  - **Is the substance/chemical named or defined under the CSA?**
  - **Need drug codes or conversion factors?**
  - **Email box: DPE@dea.gov**
- **Include:**
  - **Chemical name**
  - **Chemical structure**
- **DEA responds by letter, CC'ing the DEA Field Office**



Submit to:
DPE@DEA.gov

Request for Control Status Determination

- ✓ **Name/Company Name,**
- ✓ **Mailing Address, not just email**
- ✓ **Substance chemical name, not just acronym**
- ✓ **Substance chemical structure**

Response letter will be emailed to you

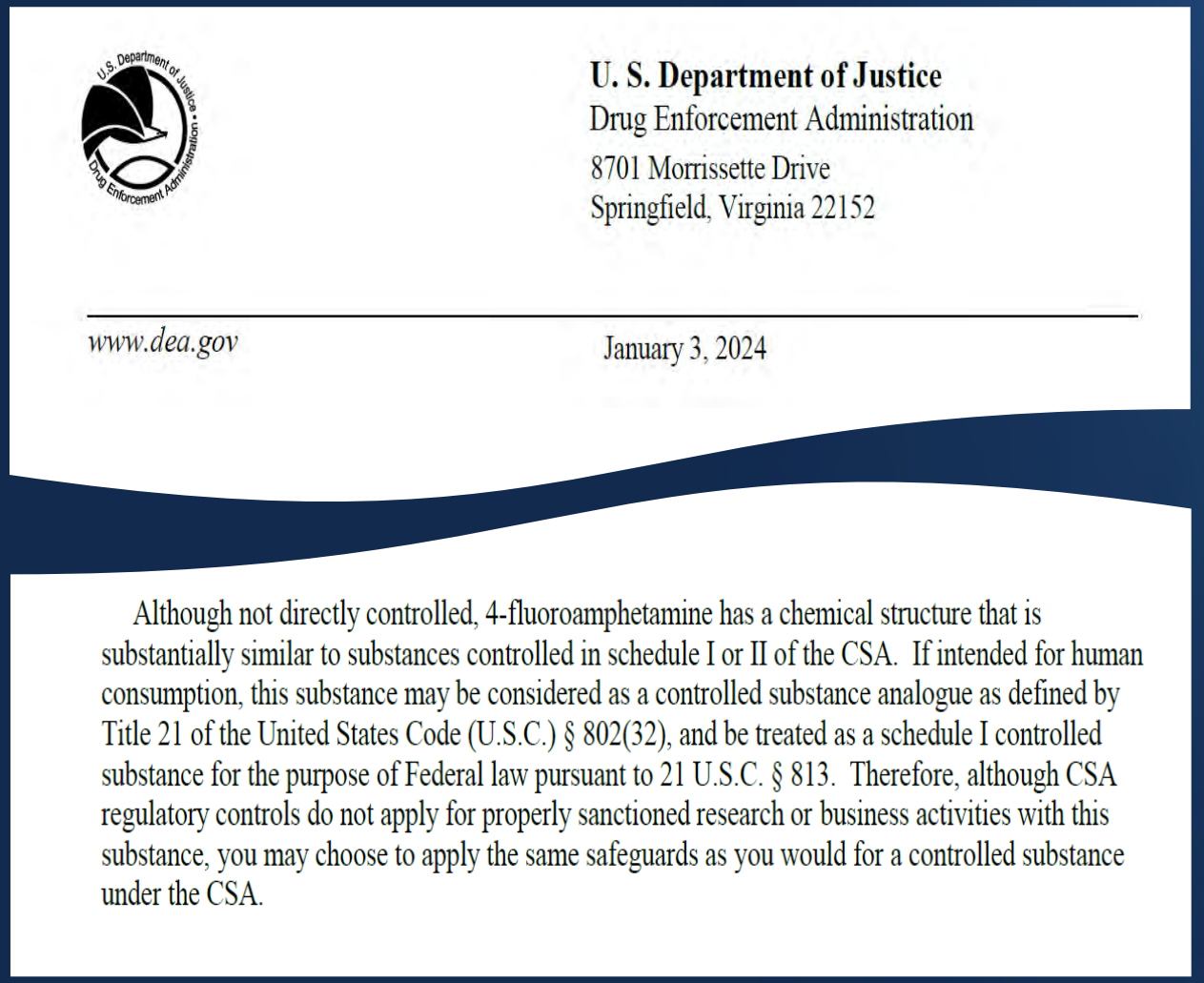
Why Analogue Language Mentioned in Letter?

21 USC § 802(32)(A)

Controlled Substance Analogue Definition

21 USC § 813(a)

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.



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

www.dea.gov

January 3, 2024

Although not directly controlled, 4-fluoroamphetamine has a chemical structure that is substantially similar to substances controlled in schedule I or II of the CSA. If intended for human consumption, this substance may be considered as a controlled substance analogue as defined by Title 21 of the United States Code (U.S.C.) § 802(32), and be treated as a schedule I controlled substance for the purpose of Federal law pursuant to 21 U.S.C. § 813. Therefore, although CSA regulatory controls do not apply for properly sanctioned research or business activities with this substance, you may choose to apply the same safeguards as you would for a controlled substance under the CSA.

Emergent Drugs are Designed to Mimic Controlled Substances and Circumvent the CSA.

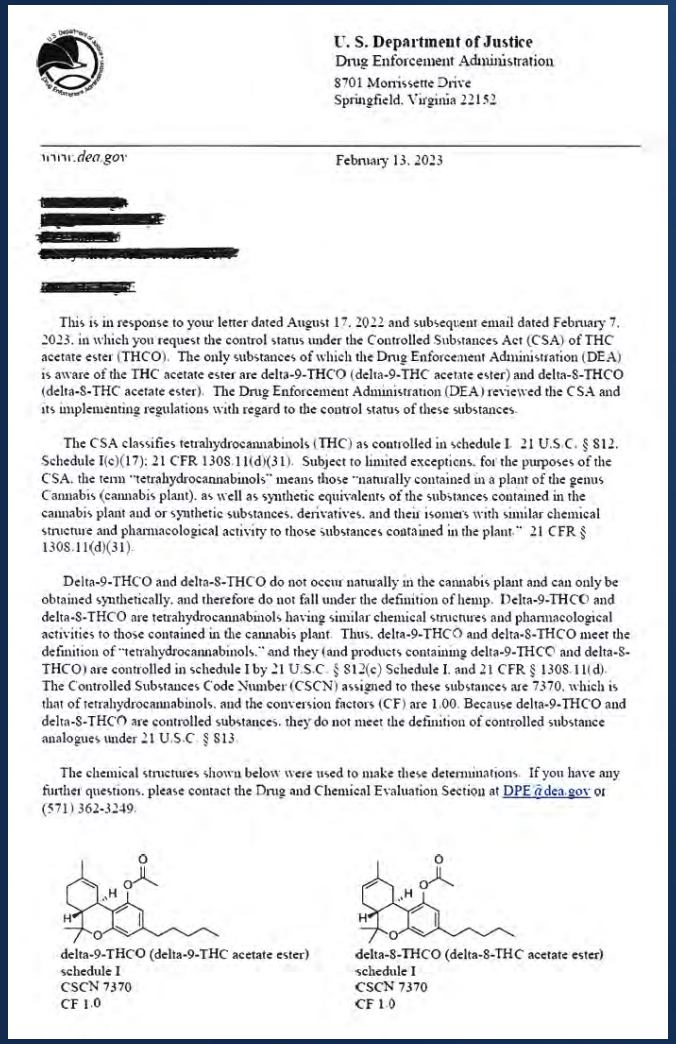
Inquiries for Status Clarification Letters

- **DOE transmits approx. 700 Control status letters/year**
  - **Don’t hesitate to follow-up for additional info or status**
- **Additionally supports DEA internally**

Example of document flow to support Import/Export Section (DRI)

AIA Control Status Inquiries

- Responding to inquiries related to Agricultural Improvement Act (AIA) control status
- Here to assist in complying with CSA requirements
  - Responded to over 150 control status inquiries
  - Primarily inquiries related to components of marijuana/hemp: CBD, Δ 8-THC, THCA, THCV, CBN, CBG, CBC, Δ10-THC, Δ8 and Δ 9-THCO, synthetic vs. natural, etc.



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February 13, 2023

[redacted]

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

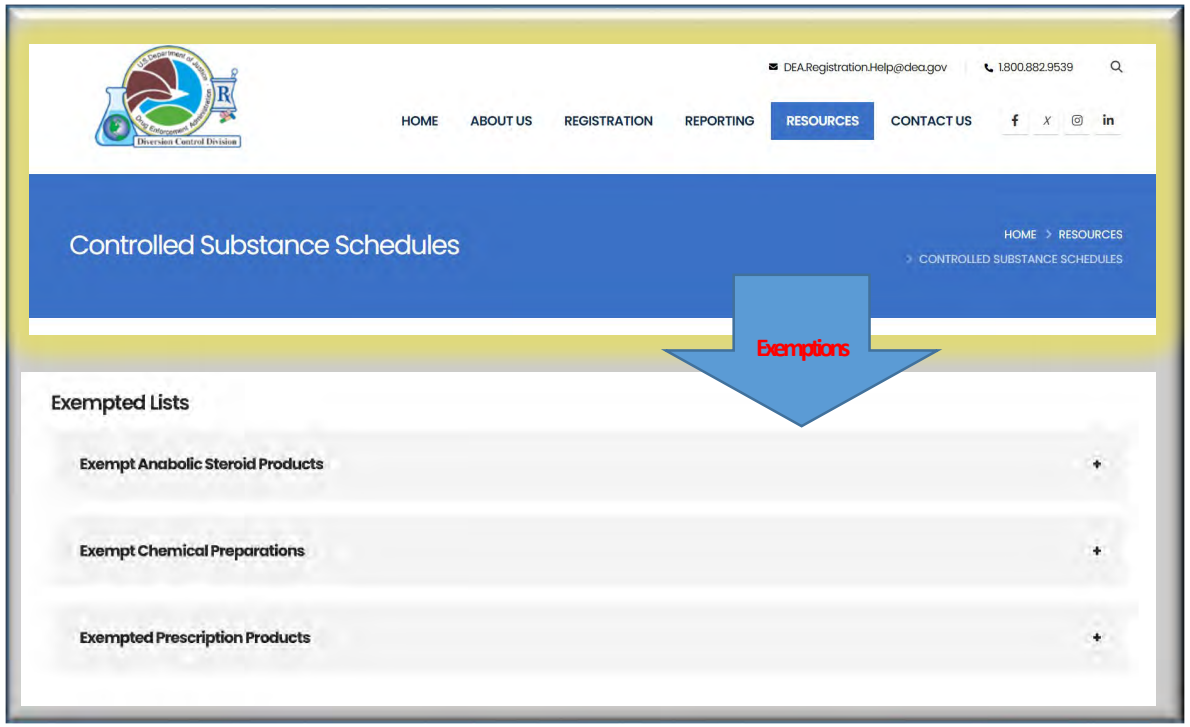
Exemptions under the CSA

Exclusion from some CSA requirements

- **Exclusion of Veterinary Anabolic Steroid Implant Products**
  (21 CFR 1308.26)
- **Anabolic Steroid Products**
  (21 CFR 1308.34)
- **Chemical Mixtures**
  (21 CFR 1310.12)
- **Chemical Preparations**
  (21 CFR 1308.24)
- **Prescription Drugs**
  (21 CFR 1308.32)

Exemption Requests, Exceptions

- Application process
- Acceptance may be required; if so, a notification is provided to the requestor
- Consultation with HHS may be required and a recommendation
- Publication of exemption
- An exemption is specific to product and substance, unless otherwise noted

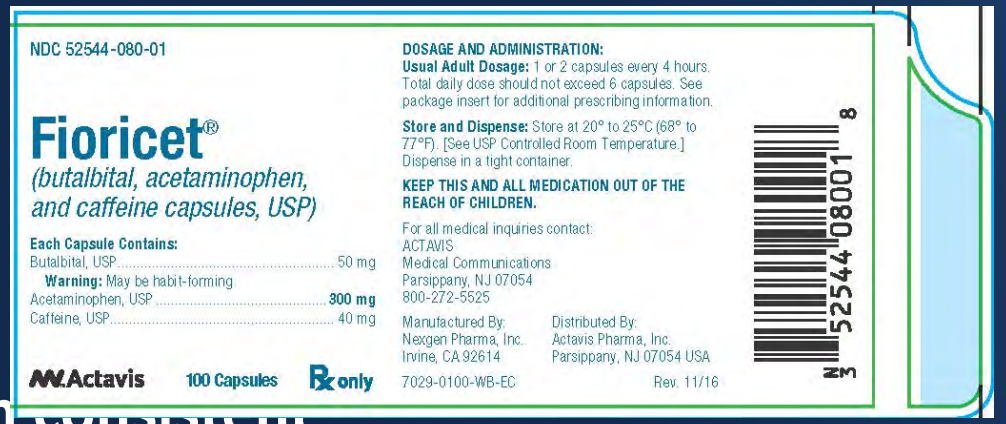


Butalbital Products Exemption

- Exemption dates back to 1967 and recommendation by a FDA panel
  - Fiorinal - CIII – butalbital (50 mg) + aspirin (325 mg) + caffeine (40 mg)
  - Fioricet - exempt – butalbital (50 mg) + acetaminophen (300 mg) + caffeine (40mg)
- Exemption used to draw users to gray market vendors
- Published notice of proposed rulemaking to remove the exemption on April 12, 2022 (started Dec 2012)
  - Collected comments (4)
  - No exemptions have been granted since May 2021
- Some manufacturers have already begun CIII labeling of previously exempt products

Butalbital Products Exemption

Exemption pre-dating the CSA



Under-rule making; intent to make them consistent

- NPRM published on April 12, 2022
- Final Rule under review