



# Status and Trends Update

## Drug & Chemical Evaluation Section

[DPE@dea.gov](mailto:DPE@dea.gov)



**Terrence Boos, Ph.D., Section Chief, Drug and Chemical Evaluation Section**



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# **Diversion Control Division**

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## **DISCLAIMER**

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**I have no financial relationships to disclose.**





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# **Diversion Control Division**

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- 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





## 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?

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Find it on e-CFR, 21 §CFR 1308

Find it in DEA Orange Book

Email [DPE@DEA.GOV](mailto:DPE@DEA.GOV)





# Online: eCFR

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 <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 Book

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



## LISTS OF: CONTROLLED SUBSTANCES SCHEDULING ACTIONS REGULATED CHEMICALS

Controlled Sub

Scheduling Action

Alphabetical Order

Chronological Order



APRIL 2022

THESE LISTS ARE ROUTINELY UPDATED THROUGHOUT THE CALENDAR YEAR  
PLEASE VISIT [HTTPS://WWW.DEA.DIVERSION.USDOJ.GOV/SCHEDULES/ORANGEBOOK/ORANGEBOOK.PDF](https://www.dea/diversion.usdoj.gov/schedules/orangebook/orangebook.pdf)  
FOR THE MOST CURRENT VERSION OF THIS PUBLICATION.

istration.Help@dea.gov | 1.800.882.9539

RESOURCES

CONTACT US



HOME > RESOURCES

> CONTROLLED SUBSTANCE SCHEDULES

Listed  
Chemicals

I and II Regulated Chemicals

Alphabetical Order

Chemical Code Number

Number

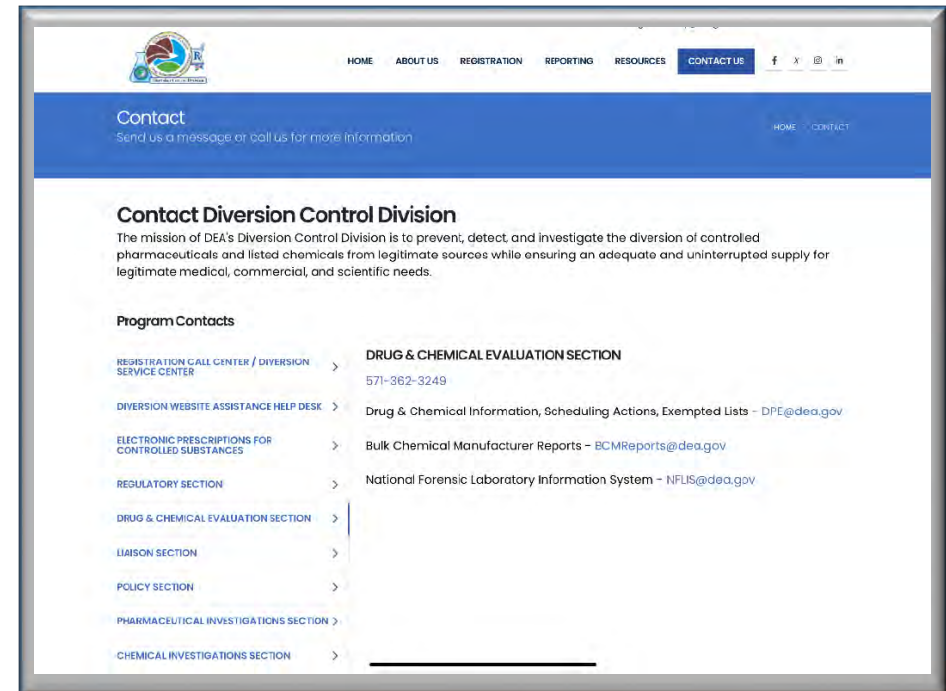
Uses and Threshold Quantities



# Control Status Inquiries



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

A screenshot of the DEA website's "Contact" page. The page has a blue header with the DEA logo and navigation links: HOME, ABOUT US, REGISTRATION, REPORTING, RESOURCES, and CONTACT US. Below the header, there is a "Contact" section with the text "Send us a message or call us for more information" and a "HOME CONTACT" link. The main content area is titled "Contact Diversion Control Division" and includes a mission statement: "The mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs." Below this is a "Program Contacts" section with a table of links and contact information.

Program Contacts	
<a href="#">REGISTRATION CALL CENTER / DIVERSION SERVICE CENTER</a>	<b>DRUG &amp; CHEMICAL EVALUATION SECTION</b> 571-362-3249
<a href="#">DIVERSION WEBSITE ASSISTANCE HELP DESK</a>	Drug & Chemical Information, Scheduling Actions, Exempted Lists - <a href="mailto:DPE@dea.gov">DPE@dea.gov</a>
<a href="#">ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES</a>	Bulk Chemical Manufacturer Reports - <a href="mailto:BCMReports@dea.gov">BCMReports@dea.gov</a>
<a href="#">REGULATORY SECTION</a>	National Forensic Laboratory Information System - <a href="mailto:NFLIS@dea.gov">NFLIS@dea.gov</a>
<a href="#">DRUG &amp; CHEMICAL EVALUATION SECTION</a>	
<a href="#">LIAISON SECTION</a>	
<a href="#">POLICY SECTION</a>	
<a href="#">PHARMACEUTICAL INVESTIGATIONS SECTION</a>	
<a href="#">CHEMICAL INVESTIGATIONS SECTION</a>	



Submit to:  
[DPE@DEA.gov](mailto:DPE@DEA.gov)

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## 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](http://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.

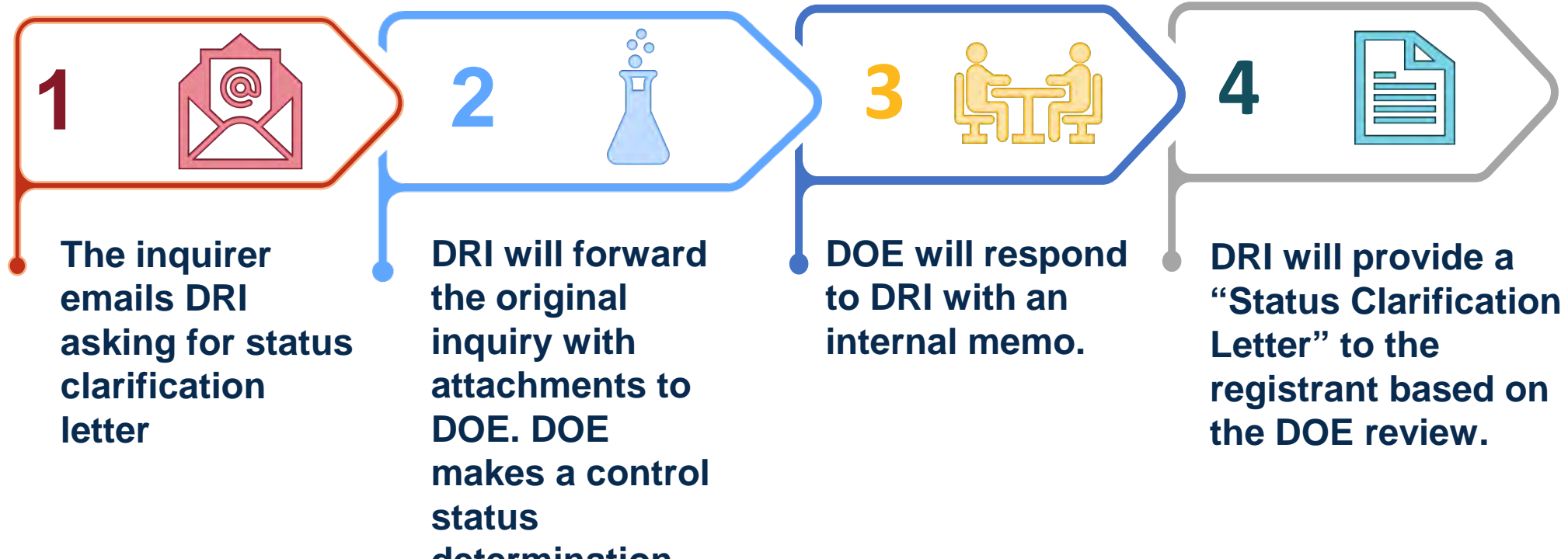
# Inquiries for Status Clarification Letters



- 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,  $\Delta$  8-THC, THCA, THCV, CBN, CBG, CBC,  $\Delta$ 10-THC,  $\Delta$ 8 and  $\Delta$  9-THCO, synthetic vs. natural, etc.

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

www.dea.gov February 13, 2023

[REDACTED]

[REDACTED]

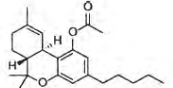
[REDACTED]

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.

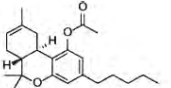
The CSA classifies tetrahydrocannabinols (THC) as controlled in schedule I, 21 U.S.C. § 812, Schedule I(c)(17); 21 CFR 1308.11(d)(31). Subject to limited exceptions, for the purposes of the CSA, the term "tetrahydrocannabinols" means those "naturally contained in a plant of the genus Cannabis (cannabis 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(e) 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](mailto: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

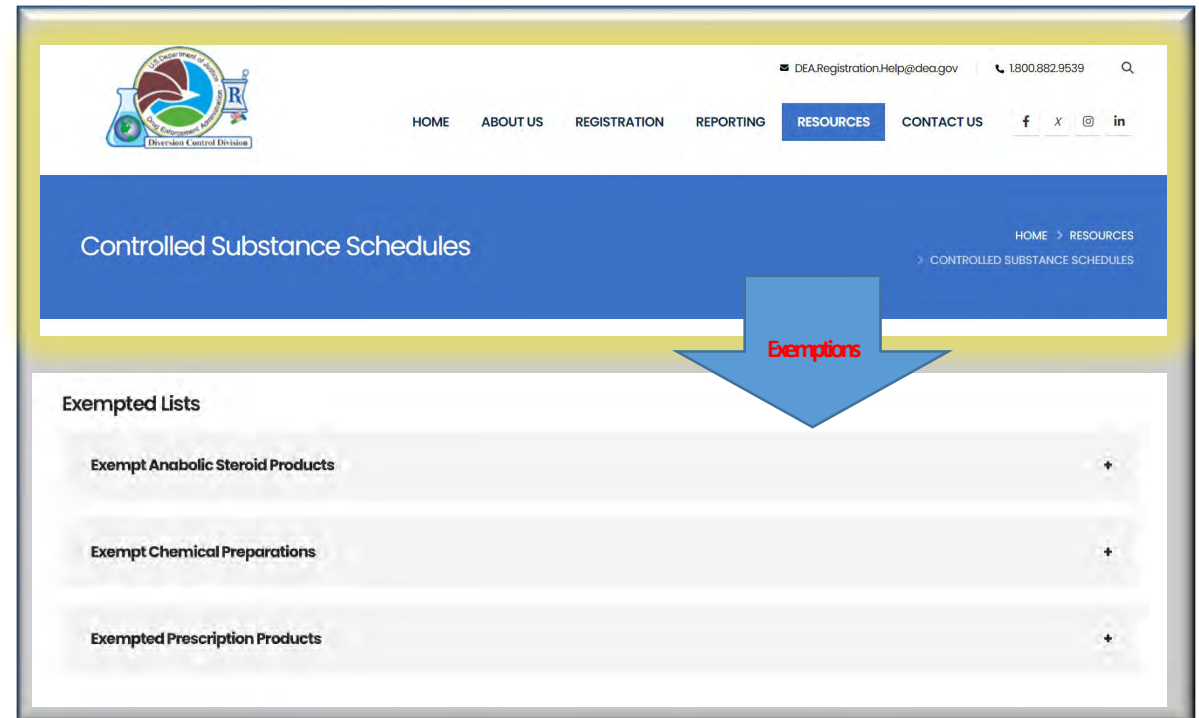
**Exclusion from some  
CSA requirements**

- **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

**Usual adult dosage:**  
1 or 2 capsules every four hours. Total daily dose should not exceed 6 capsules.

**Store and dispense:**  
Below 25°C (77°F); tight container. Protect from moisture.

**Keep out of reach of children.**

Distributed by:  
Allergan USA, Inc.  
Irvine, CA 92612

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Made in USA

NDC 0023-6146-01

**Fiorinal®**  
(Butalbital, Aspirin, and Caffeine Capsules, USP)

Each capsule contains:  
butalbital, USP.....50 mg  
aspirin, USP.....325 mg  
caffeine, USP.....40 mg

**Rx only**

100 Capsules

Allergan™

55745US10

190105-3

3 00236 14601 6

NDC 52544-080-01

**Fioricet®**  
(butalbital, acetaminophen, and caffeine capsules, USP)

**DOSAGE AND ADMINISTRATION:**  
**Usual Adult Dosage:** 1 or 2 capsules every 4 hours. Total daily dose should not exceed 6 capsules. See package insert for additional prescribing information.

**Store and Dispense:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Dispense in a tight container.

**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

For all medical inquiries contact:  
ACTAVIS  
Medical Communications  
Parsippany, NJ 07054  
800-272-5525

Manufactured By:  
Nexgen Pharma, Inc.  
Irvine, CA 92614

Distributed By:  
Actavis Pharma, Inc.  
Parsippany, NJ 07054 USA

7029-0100-WB-EC

Rev. 11/16

Each Capsule Contains:  
Butalbital, USP.....50 mg  
Acetaminophen, USP.....300 mg  
Caffeine, USP.....40 mg

**Warning:** May be habit-forming

**Actavis** 100 Capsules **Rx only**

52544-08001-8

Under-rule making; intent to make them consistent

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