



Chemical Controls

Virtual Chemical Industry Conference
April 20, 2025

Trudy Amin, Ph.D.
Drug and Chemical Evaluation Section
Diversion Control Division
Drug Enforcement Administration



Overview

- Section Overview
- Controlled Substances Act and Chemical Regulations
- Recent Control Actions
- Looking Ahead
- Special Surveillance List
- Exemptions



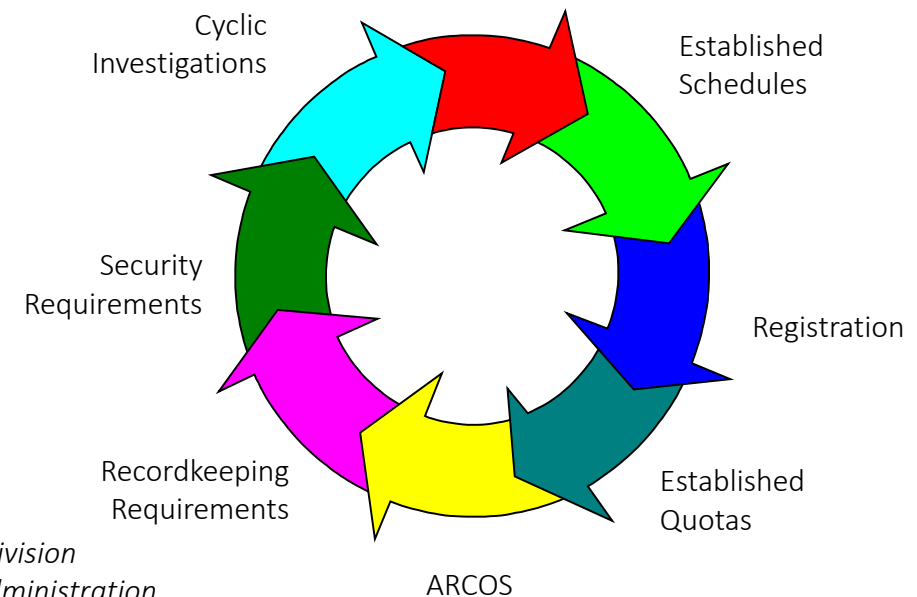
DOE is responsible for evaluating drugs and chemicals to determine whether these substances are being abused or potentially involved in illicit traffic. These evaluations are used by DEA as a basis for developing appropriate drug control policies, determining the status of controlled, excluded, or exempted drugs and drug products; and supporting U.S. initiatives in international forums.



U.S. Controlled Substances Act (1970)



- To control and regulate the licit and illicit trade in and use of such substances
- To implement the international obligation under the Single Convention on Narcotic Drugs 1961 which restricts the use of controlled substances to legitimate medical and scientific purposes
- Substances with abuse potential are placed in 1 of 5 schedules

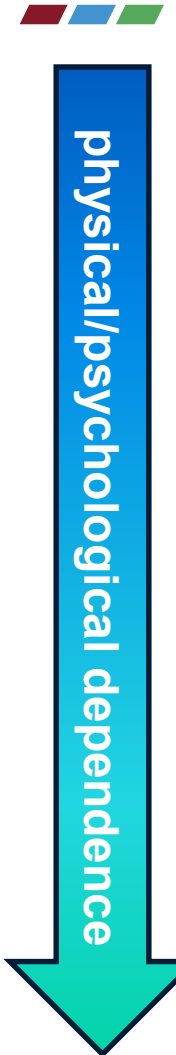
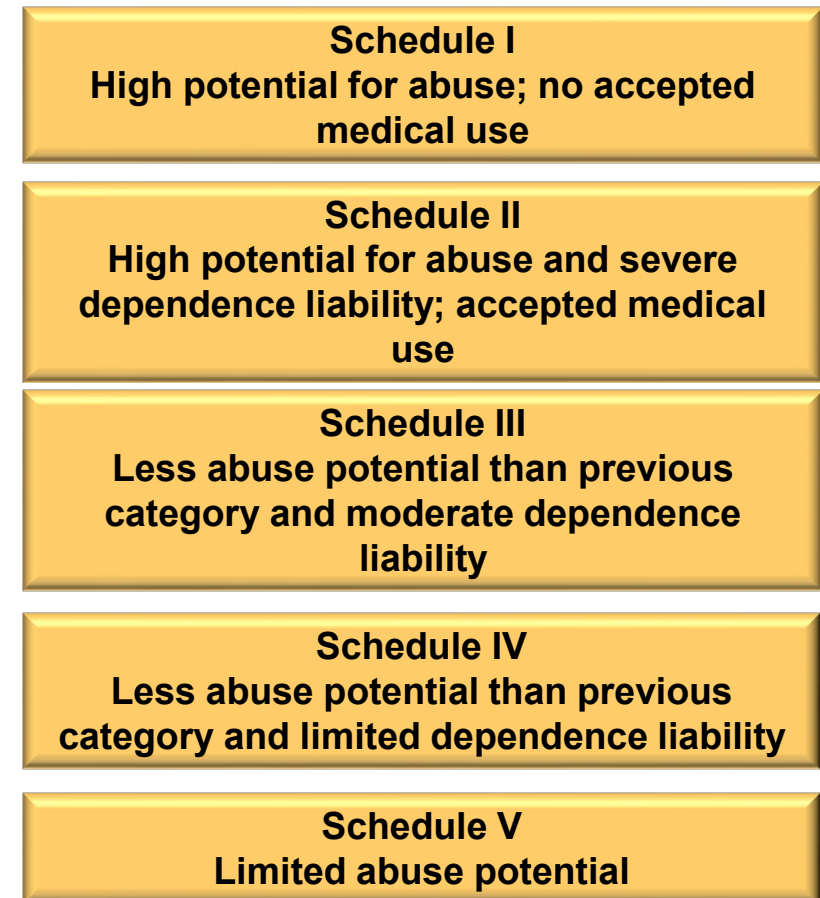


*Diversion Control Division
U.S. Drug Enforcement Administration*

Controlled Substances Act (CSA)



- **Places substances into a 1 of 5 schedules per their abuse liability**
 - Schedule I – No approved medical use, high abuse potential
 - Schedule II – Approved medical use, high abuse potential
 - Schedule III
 - Schedule IV
 - Schedule V
- **Ensures an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs**



Chemical Regulations



- Section 1310.02 of Title 21 Code of Federal Regulations (21 CFR § 1310.02)
 - Chemicals used to synthesize drugs, purify/extract, or convert into abusable form
 - Total of 50 List I and II chemicals
 - Additions/changes/removals published in the Federal Register
- List I chemical handlers (Importers/Exporters/Manufacturers/Distributors) must:
 - Register
 - Maintain records
 - Report suspicious orders
- DEA routinely inspects records and required controls. Through industry outreach and voluntary compliance measures, DEA strives to control chemical diversion in partnership with industry and the public.

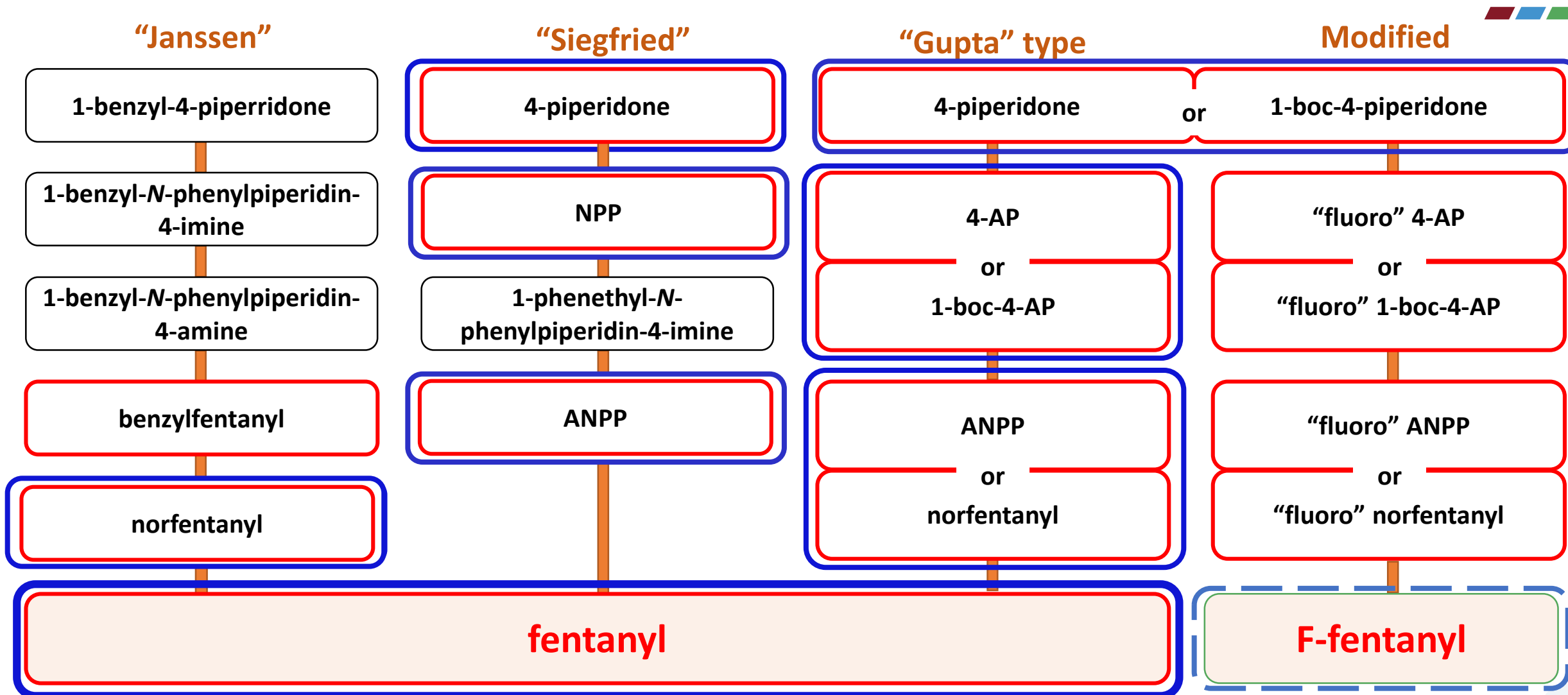


Regulated Chemicals - List I



- (1) Alpha-phenylacetoacetonitrile (APAAN) salts, optical isomers
- (2) Anthranilic acid, its esters, and its salts
- (3) Benzyl cyanide
- (4) Ephedrine, its salts, optical isomers
- (5) Ergonovine and its salts
- (6) Ergotamine and its salts
- (7) N-Acetylanthranilic acid, its esters, and its salts
- (8) Norpseudoephedrine, its salts, optical isomers,
- (9) Phenylacetic acid, its esters, and its salts
- (10) Phenylpropanolamine, its salts, optical isomers
- (11) Piperidine and its salts
- (12) Pseudoephedrine, its salts, optical isomers
- (13) 3,4-Methylenedioxyphenyl-2-propanone
- (14) Methylamine and its salts
- (15) Ethylamine and its salts
- (16) Propionic anhydride
- (17) Isosafrole
- (18) Safrole
- (19) Piperonal
- (20) N-Methylephedrine, its salts, optical isomers
- (21) N-Methylpseudoephedrine, its salts, optical isomers
- (22) Hydriodic Acid
- (23) Benzaldehyde
- (24) Nitroethane
- (25) Gamma-Butyrolactone
- (26) Red phosphorus
- (27) White phosphorus
- (28) Hypophosphorous acid and its salts
- (29) N-phenethyl-4-piperidone (NPP)
- (30) Iodine
- (31) Ergocristine and its salts
- (32) N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide (benzylfentanyl) and its salts
- (33) N-phenylpiperidin-4-amine (4-AP), its amides, its carbamates, its halides, its salts, and any combination
- (34) 3,4-MDP-2-P methyl glycidate (PMK glycidate) and its optical and geometric isomers
- (35) 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid) and its salts, optical and geometric isomers, and salts of isomers
- (36) Alpha-phenylacetoacetamide (APAA) and its optical isomers
- (37) methyl alpha-phenylacetoacetate (MAPA), its optical isomers
- (38) 4-piperidone (piperidin-4-one), its acetals, its amides, its carbamates, its salts
- (39) 1-boc-4-AP (tert-butyl 4-(phenylamino)piperidine-1-carboxylate) and its salts

Chemical Controls- Fentanyl Manufacture Pathways



Chemical Controls- Control of 4-AP in List I of CSA



4-Anilinopiperidine (4-AP), its **amides**, its **carbamates**, and its salts



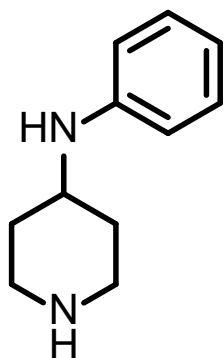
FEDERAL REGISTER
The Daily Journal of the United States Government



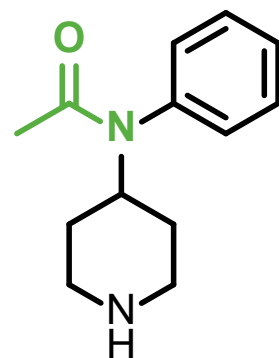
® Rule

Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals

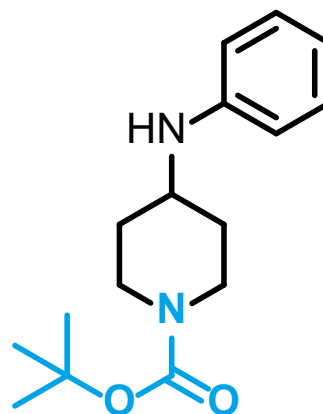
A Rule by the Drug Enforcement Administration on 04/15/2020



4-AP



acetyl
norfentanyl



1-Boc-4-AP

Others captured:

- ethyl 4-AP-1-carboxylate
- 1-Cbz-4-AP
- furanyl norfentanyl
- butyryl norfentanyl
- cyclopropyl norfentanyl
- valeryl norfentanyl
- isobutyryl norfentanyl

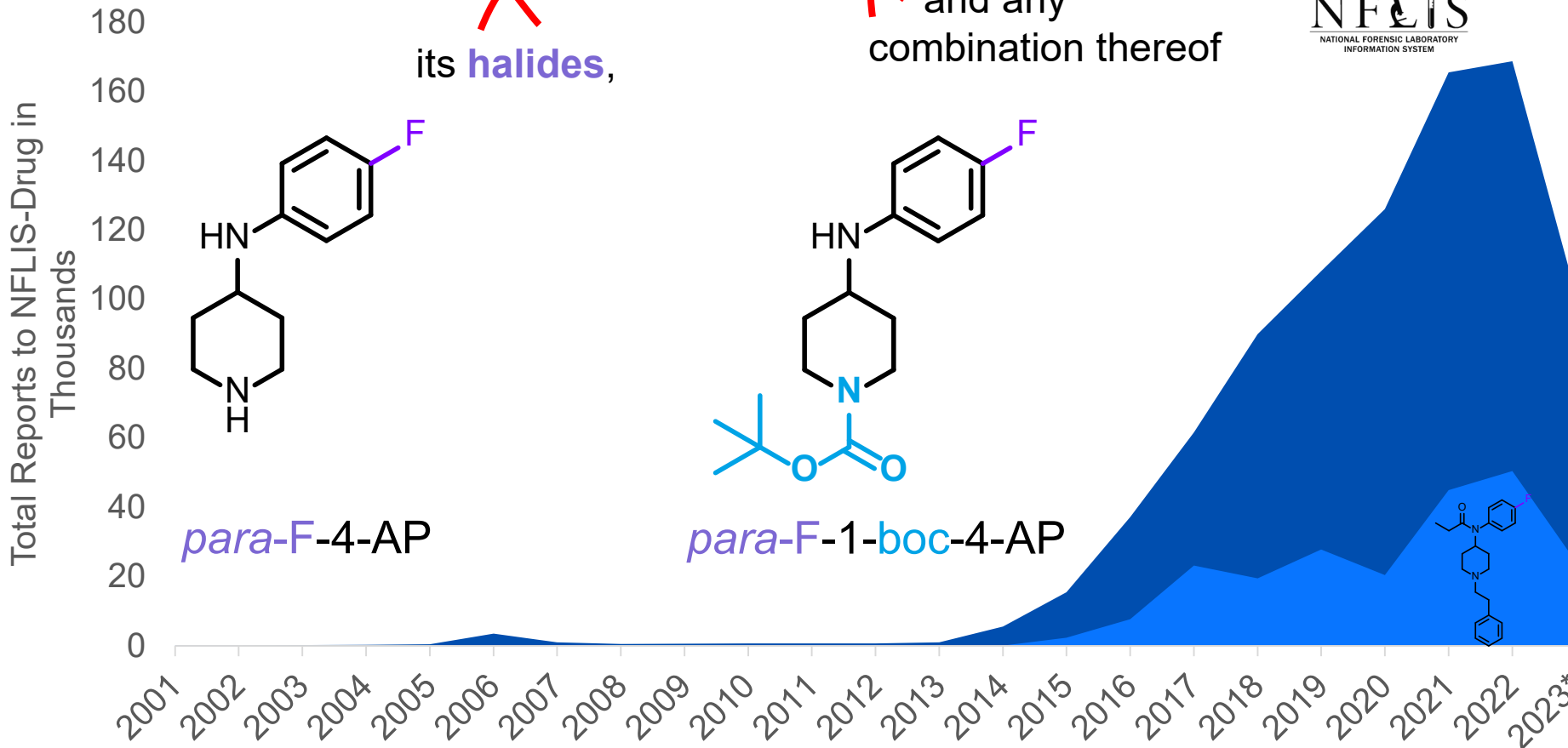
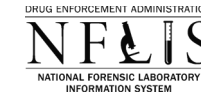
Chemical Controls- Fentanyl Precursors



4-Anilinopiperidine (4-AP), its amides, its carbamates, and its salts

its halides,

and any combination thereof



88 FR 74352:

Designation of Halides of 4-Anilinopiperidine as List I Chemicals

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1098]

Designation of Halides of 4-Anilinopiperidine as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

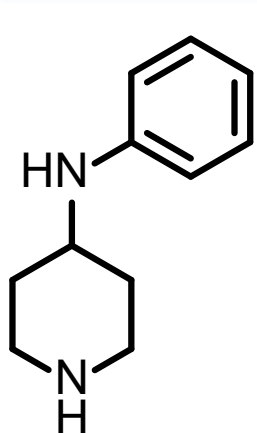
SUMMARY: The Drug Enforcement Administration (DEA) is finalizing the modification of the listing of the list I chemical, *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4-AP) (hereinafter referred to as 4-anilinopiperidine), to include halides of 4-anilinopiperidine. This rule finalizes the modification of the listing of 4-anilinopiperidine as a list I chemical.

DATES: This rule is effective November 30, 2023. Persons currently

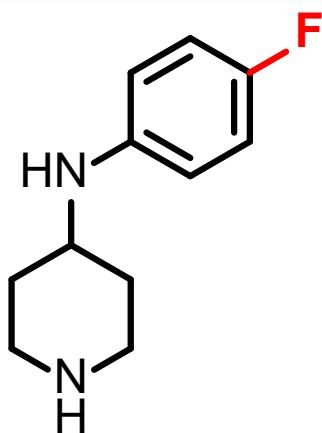
Chemical Controls- Control of Halides of 4-AP in List I of CSA



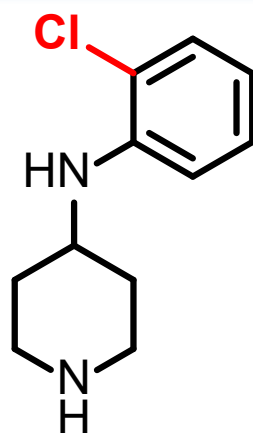
4-Anilinopiperidine (4-AP), its **amides**,
its **carbamates**, its **halides**, its salts,
and any combination thereof



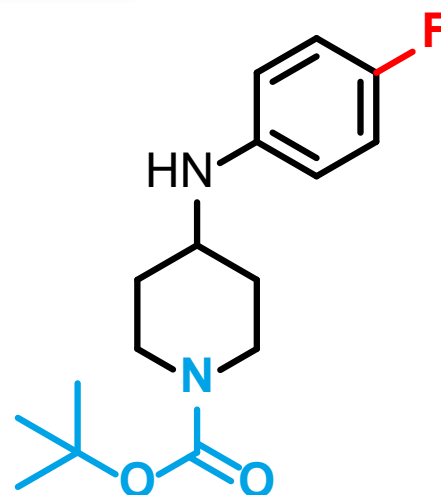
4-AP



para-fluoro 4-AP



ortho-chloro 4-AP



para-fluoro 1-**Boc** 4-AP

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

21 CFR Part 1310
[Docket No. DEA-1098]

Designation of Halides of 4-Anilinopiperidine as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

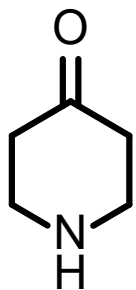
SUMMARY: The Drug Enforcement Administration (DEA) is finalizing the modification of the listing of the list I chemical, *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4-AP) (hereinafter referred to as 4-anilinopiperidine), to include halides of 4-anilinopiperidine. This rule finalizes the modification of the listing of 4-anilinopiperidine as a list I chemical.

Effective Date: November 30, 2023

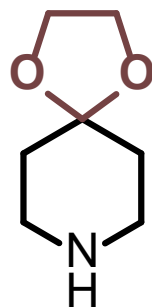
Chemical Controls- 4- Piperidone



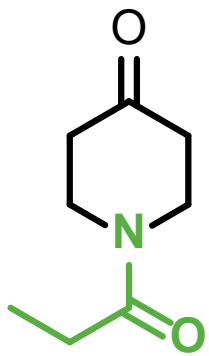
4-Piperidone, its **acetals**, its **amides**, its **carbamates**, its salts, and salts of its acetals, its amides, and its carbamates, and any combination thereof



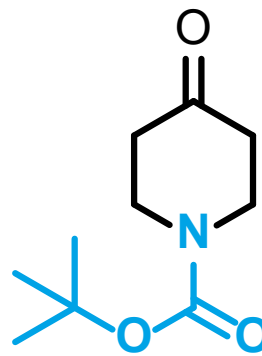
4-piperidone



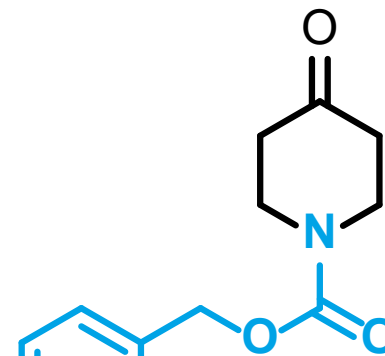
4-piperidone
ethylene ketal



1-propionyl-
4-piperidone



1-boc-4-
piperidone



1-Cbz-4-
piperidone

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-951]

Designation of 4-Piperidone as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

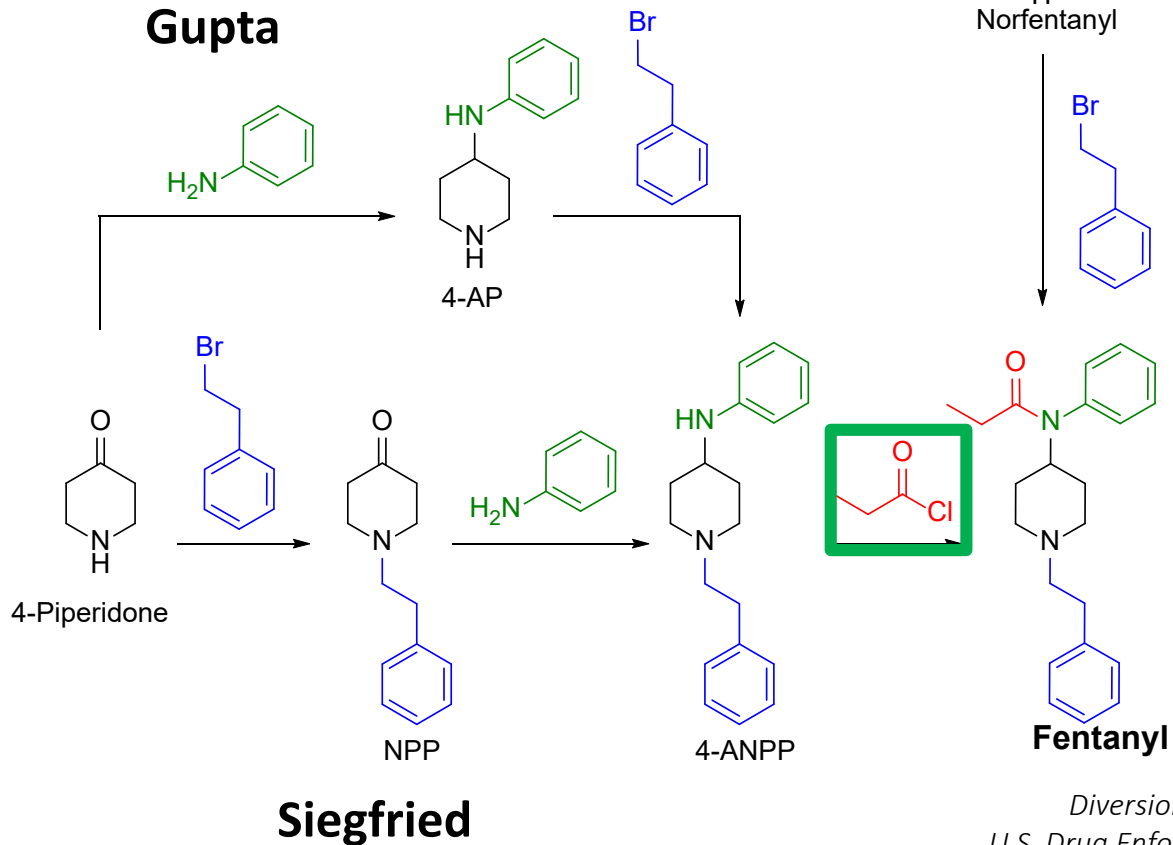
SUMMARY: The Drug Enforcement Administration (DEA) is finalizing the control of 4-piperidone, its acetals, its amides, its carbamates, its salts, and salts of its acetals, its amides, and its carbamates, and any combination thereof, whenever the existence of such is possible, as a list I chemical under the Controlled Substances Act. DEA proposed control of 4-piperidone due to its use in clandestine laboratories to illicitly manufacture the schedule II controlled substance fentanyl. This rulemaking finalizes the control of 4-piperidone as a list I chemical.

DATES: This rulemaking is effective on May 12, 2023. Persons seeking

Looking Ahead- Propionyl Chloride



Published Advanced Notice Proposed Rule Making (ANPRM)



Diversion Control Division
U.S. Drug Enforcement Administration

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

21 CFR Part 1310
[Docket No. DEA-1189]

Propionyl Chloride

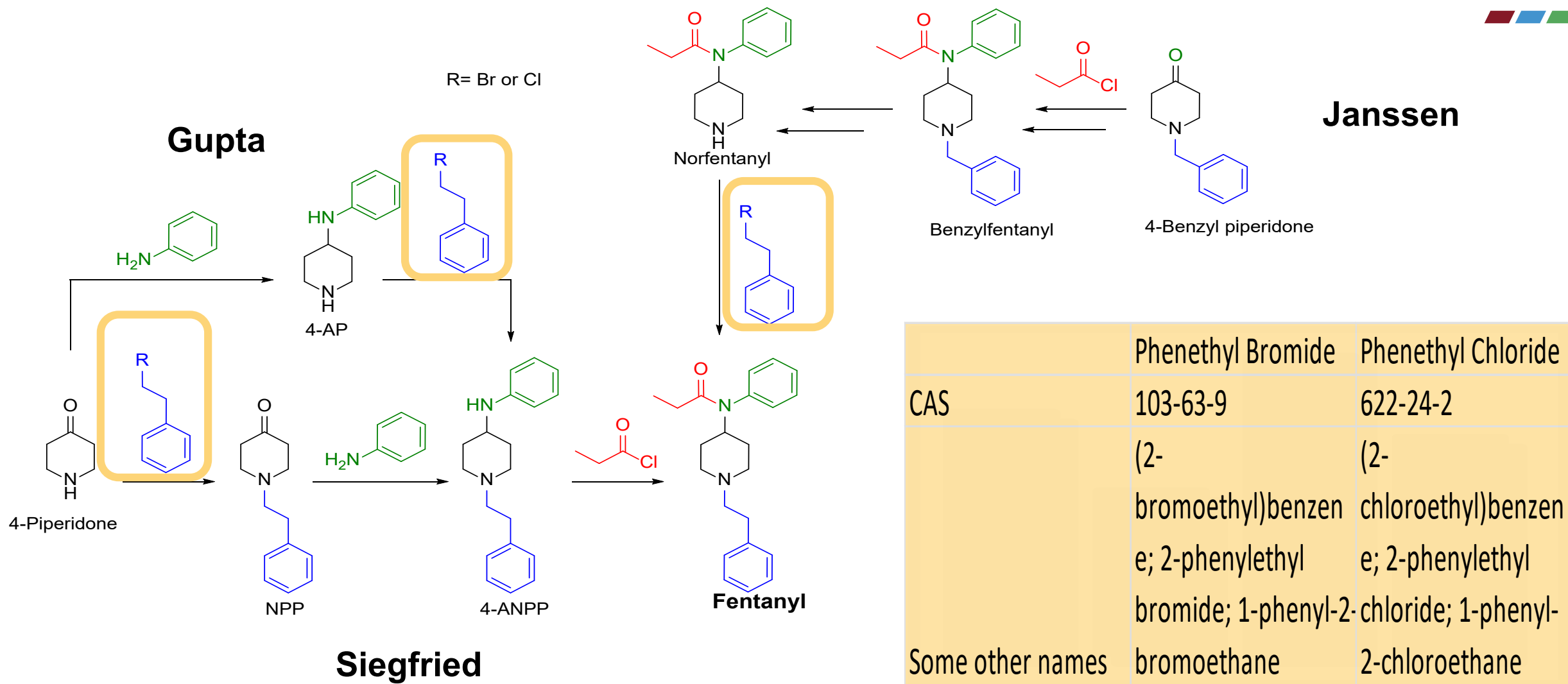
AGENCY: Drug Enforcement
Administration, Department of Justice.

ACTION: Advanced notice of proposed
rulemaking.

SUMMARY: The Drug Enforcement
Administration finds that propionyl
chloride is used in the illicit
manufacture of the controlled substance
fentanyl, as well as fentanyl analogues,
and fentanyl-related substances and is
important to the manufacture of these
substances because it is often used in
synthetic pathways to illicitly

Published: October 12, 2023

Looking Ahead- Phenethyl Halides

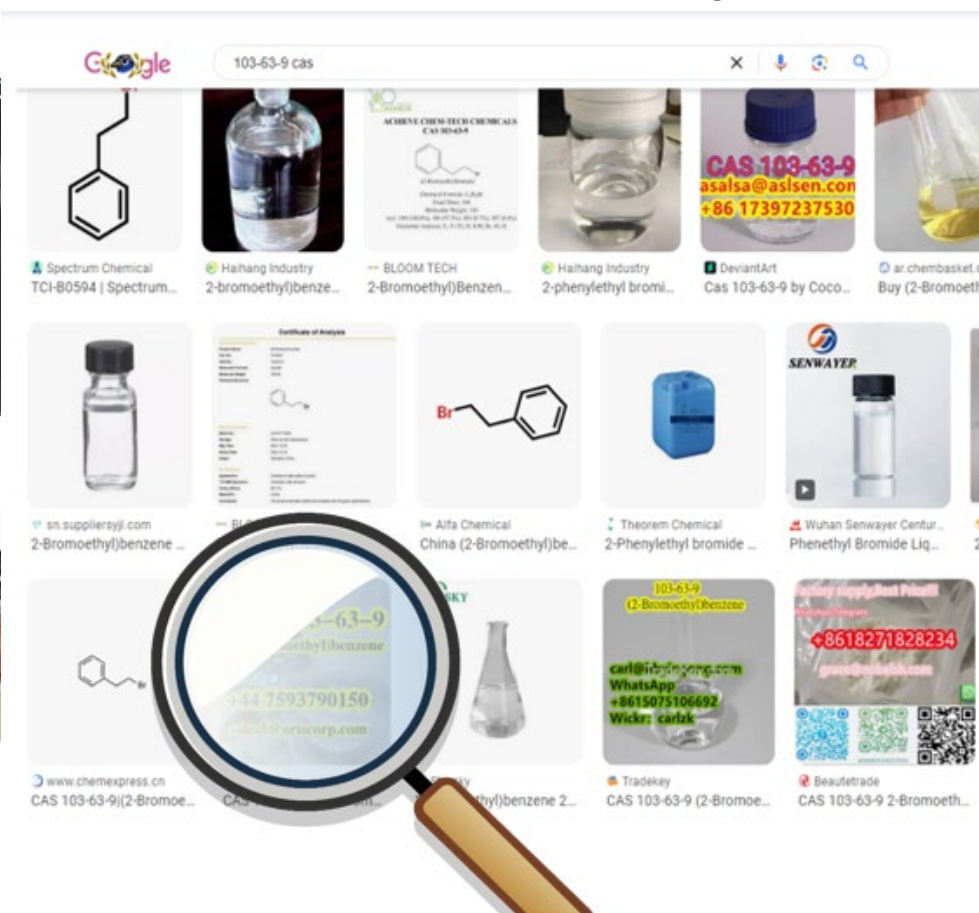


Looking Ahead- Phenethyl Halides



Chemicals easily found on the internet

CAS # Search on Google



Published Advanced Notice Proposed Rule Making (ANPRM)

Published: October 28, 2024

DEPARTMENT OF JUSTICE Drug Enforcement Administration

21 CFR Part 1310
[Docket No. DEA-1282]

Possible Control of Phenethyl Bromide as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) finds that phenethyl bromide is used in the illicit manufacture of the controlled substance fentanyl, as well as fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances because it is often used in synthetic pathways to illicitly manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. Prior to proposing to list phenethyl bromide as a list I chemical under the Controlled Substances Act, DEA is soliciting information on the current uses of phenethyl bromide (other than for the synthesis of fentanyl) in order to properly determine the effect such a proposed action would have on legitimate industry.

Looking Ahead- Industry Input



* * * * *

Issued in Washington, DC, on October 22, 2024.
Frank Lias,
Manager, Rules and Regulations Group.
[FR Doc. 2024-24938 Filed 10-25-24; 8:45 am]
BILLING CODE 4910-13-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1282]

Possible Control of Phenethyl Bromide as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) finds that phenethyl bromide is used in the illicit manufacture of the controlled substance fentanyl, as well as fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances because it is often used in synthetic pathways to illicitly manufacture fentanyl, fentanyl analogues, and fentanyl-related substances. Prior to proposing to list phenethyl bromide as a list I chemical under the Controlled Substances Act, DEA is soliciting information on the current uses of phenethyl bromide (other than for the synthesis of fentanyl) in order to properly determine the effect such a proposed action would have on legitimate industry.

DATES: Comments must be submitted electronically or postmarked on or before November 27, 2024. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-1282" on all electronic and

written correspondence, including any attachments.

- **Electronic comments:** The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your comment submission, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](https://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- **Paper comments:** Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make comments available for public inspection online at <https://www.regulations.gov>. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information

Comment period for control actions

- Allows public to provide information related the proposed action
- Companies can provide information about uses and impact (if any) on their business
- Information helps inform control policies

Industry input needed!

Diversion Control Division
U.S. Drug Enforcement Administration

Special Surveillance List - Comprehensive Methamphetamine Control Act, CMCA 1996



Public Law 104-237
104th Congress

An Act

To prevent the illegal manufacturing and use of methamphetamine.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Comprehensive Methamphetamine Control Act of 1996”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

- Sec. 1. Short title and table of contents.
- Sec. 2. Findings.

TITLE I—IMPORTATION OF METHAMPHETAMINE AND PRECURSOR CHEMICALS

- Sec. 101. Support for international efforts to control drugs.
- Sec. 102. Penalties for manufacture of listed chemicals outside the United States with intent to import them into the United States.

TITLE II—PROVISIONS TO CONTROL THE MANUFACTURE OF METHAMPHETAMINE

- Sec. 201. Seizure and forfeiture of regulated chemicals.
- Sec. 202. Study and report on measures to prevent sales of agents used in methamphetamine production.
- Sec. 203. Increased penalties for manufacture and possession of equipment used to make controlled substances.
- Sec. 204. Addition of iodine and hydrochloric gas to list II.
- Sec. 205. Civil penalties for firms that supply precursor chemicals.
- Sec. 206. Injunctive relief.
- Sec. 207. Restitution for cleanup of clandestine laboratory sites.
- Sec. 208. Record retention.
- Sec. 209. Technical amendments.
- Sec. 210. Withdrawal of regulations.

TITLE III—INCREASED PENALTIES FOR TRAFFICKING AND MANUFACTURE OF METHAMPHETAMINE AND PRECURSORS

- Sec. 301. Penalty increases for trafficking in methamphetamine.
- Sec. 302. Enhanced penalties for offenses involving certain listed chemicals.
- Sec. 303. Enhanced penalty for dangerous handling of controlled substances: amendment of sentencing guidelines.

Oct. 3, 1996
[S. 1965]

Comprehensive
Methamphetamine Control
Act of 1996.
21 USC 801 note.



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The Daily Journal of the United States Government



Notice

Special Surveillance List of Chemicals, Products, Materials and Equipment Used in the Clandestine Production of Controlled Substances or Listed Chemicals

A Notice by the [Drug Enforcement Administration](#) on 05/13/1999



FEDERAL REGISTER

The Daily Journal of the United States Government



Notice

Special Surveillance List of Chemicals, Products, Materials and Equipment Used in the Manufacture of Controlled Substances and Listed Chemicals

A Notice by the [Drug Enforcement Administration](#) on 10/24/2023



Special Surveillance List (SSL)



Chemicals, including their salts whenever the existence of such salts is possible:

- All listed chemicals as specified in 21 CFR 1310.02(a) or (b). This includes all chemical mixtures and all over-the-counter (OTC) products and dietary supplements which contain a listed chemical, regardless of their dosage form or packaging and regardless of whether the chemical mixture, drug product or dietary supplement is exempt from regulatory controls.
- **1,1'-carbonyldiimidazole**
- **1,1-dichloro-1-fluoroethane (e.g., Freon 141B)**
- **2,5-dimethoxyphenethylamine**
- **ammonia gas**
- **ammonium formate**
- **bromobenzene**
- **cyclohexanone**
- **diethylamine and its salts**

- **formamide**
- **formic acid**
- **lithium aluminum hydride**
- **lithium metal**
- **magnesium metal (turnings)**
- **mercuric chloride**
- **N-methylformamide**
- **organomagnesium halides (Grignard reagents) (e.g., ethylmagnesium bromide and phenylmagnesium bromide)**
- **ortho-toluidine**
- **phenylethanolamine and its salts**
- **phosphorus pentachloride**
- **potassium dichromate**
- **pyridine and its salts**
- **sodium dichromate**
- **sodium metal**
- **thionyl chloride**
- **trichloromonofluoromethane (e.g., Freon-11, Carrene-2)**
- **trichlorotrifluoroethane (e.g., Freon 113)**

effective 5/13/1999

Equipment:

- **hydrogenators**
- **tableting machines**
- **encapsulating machines**
- **22 liter heating mantels**

Special Surveillance List - Updates



- Updated original listing from 1999
- Published June 16, 2023
 - Expanded # of chemicals
 - Additional equipment
- Notice received 29 comments

<https://www.govinfo.gov/content/pkg/FR-2023-06-16/pdf/2023-12893.pdf>

Significance



- Reaffirms:
manufacturers/distributors
should know their customer
- Fine up to \$470K for
distribution to an entity uses
in the manufacture of
controlled substance



Special Surveillance List (SSL)



Chemicals, including their salts whenever the existence of such salts is possible:

- All listed chemicals as specified in 21 CFR 1310.02(a) or (b). This includes all chemical mixtures and all over-the-counter (OTC) products and dietary supplements which contain a listed chemical, regardless of their dosage form or packaging and regardless of whether the chemical mixture, drug product or dietary supplement is exempt from regulatory controls.
- (2-nitroprop-1-en-1-yl)benzene (1-phenyl-2-nitropropene; P2NP)
- 1-(4-bromophenyl)propan-1-one
- 1-(4-chlorophenyl)propan-1-one
- 1-(4-methylphenyl)propan-1-one
- 1,1'-carbonyldiimidazole
- 1,1-dichloro-1-fluoroethane (e.g., Freon 141B)
- 1-benzylpiperidin-4-one (*N*-benzyl-4-piperidone)
- 1-chloro-*N*-methyl-1-phenylpropan-2-amine (chloroephedrine; chloropseudoephedrine)
- 1-phenylbutan-1-one
- 1-phenylpentan-1-one
- 1-phenylpropan-1-one
- 2,5-dimethoxyphenethylamine
- 2-bromo-1-(4-chlorophenyl)propan-1-one
- 2-bromo-1-(4-methoxyphenyl)propan-1-one
- 2-bromo-1-(4-methylphenyl)propan-1-one
- 2-bromo-1-phenylpentan-1-one
- 2-bromo-1-phenylpropan-1-one
- 3-methyl-3-phenyloxirane-2-carboxylic acid (BMK glycidic acid; P2P glycidic acid) and its esters (e.g., methyl 3-methyl-3-phenyloxirane-2-carboxylate (BMK methyl glycidate); ethyl 3-methyl-3-phenyloxirane-2-carboxylate (BMK ethyl glycidate))
- 3-oxo-2-phenylbutanoic acid and its esters (e.g., alpha-phenylacetoacetic acid; ethyl 3-oxo-2-phenylbutanoate (EAPA))
- 5-(2-nitroprop-1-en-1-yl)benzodioxole (3,4-methylenedioxyphenyl-2-nitropropene; 3,4-MDP2NP)
- ammonia gas
- ammonium formate
- azobisisobutyronitrile
- bromobenzene
- butane-1,4-diol (1,4-butanediol)
- cyclohexanone
- diethylamine and its salts

- ethyl 3-oxo-4-phenylbutanoate
- ethyl-3-(1,3-benzodioxol-5-yl)-2-methyloxirane-2-carboxylate (3,4-MDP-2-P ethyl glycidate)
- formamide
- formic acid
- lithium aluminum hydride
- lithium metal
- magnesium metal (turnings)
- mercuric chloride
- methyl 2-(1,3-benzodioxol-5-yl)-3-oxobutanoate (MAMDPA; MDMAPA)
- *N*-methylformamide
- organomagnesium halides (Grignard reagents) (e.g., ethylmagnesium bromide and phenylmagnesium bromide)
- *ortho*-toluidine
- phenethyl bromide ((2-bromoethyl)benzene)
- phenylethanolamine and its salts
- phosphorus pentachloride
- potassium dichromate
- propionyl chloride
- pyridine and its salts
- sodium borohydride
- sodium dichromate
- sodium metal
- sodium triacetoxymethylborohydride
- *tert*-butyl 4-((4-fluorophenyl)amino)piperidine-1-carboxylate (*para*-fluoro 1-boc-4-AP)
- thioglycolic acid and its esters (e.g., methyl thioglycolate)
- thionyl chloride
- trichloromonofluoromethane (e.g., Freon-11, Carrene-2)
- trichlorotrifluoroethane (e.g., Freon 113)

Equipment:

- hydrogenators
- tableting machines, including punches and dies
- encapsulating machines
- 22 liter heating mantels

effective 10/24/2023



Civil Penalty – Controlled Substances Act (CSA)

21 USC 842: Prohibited acts B

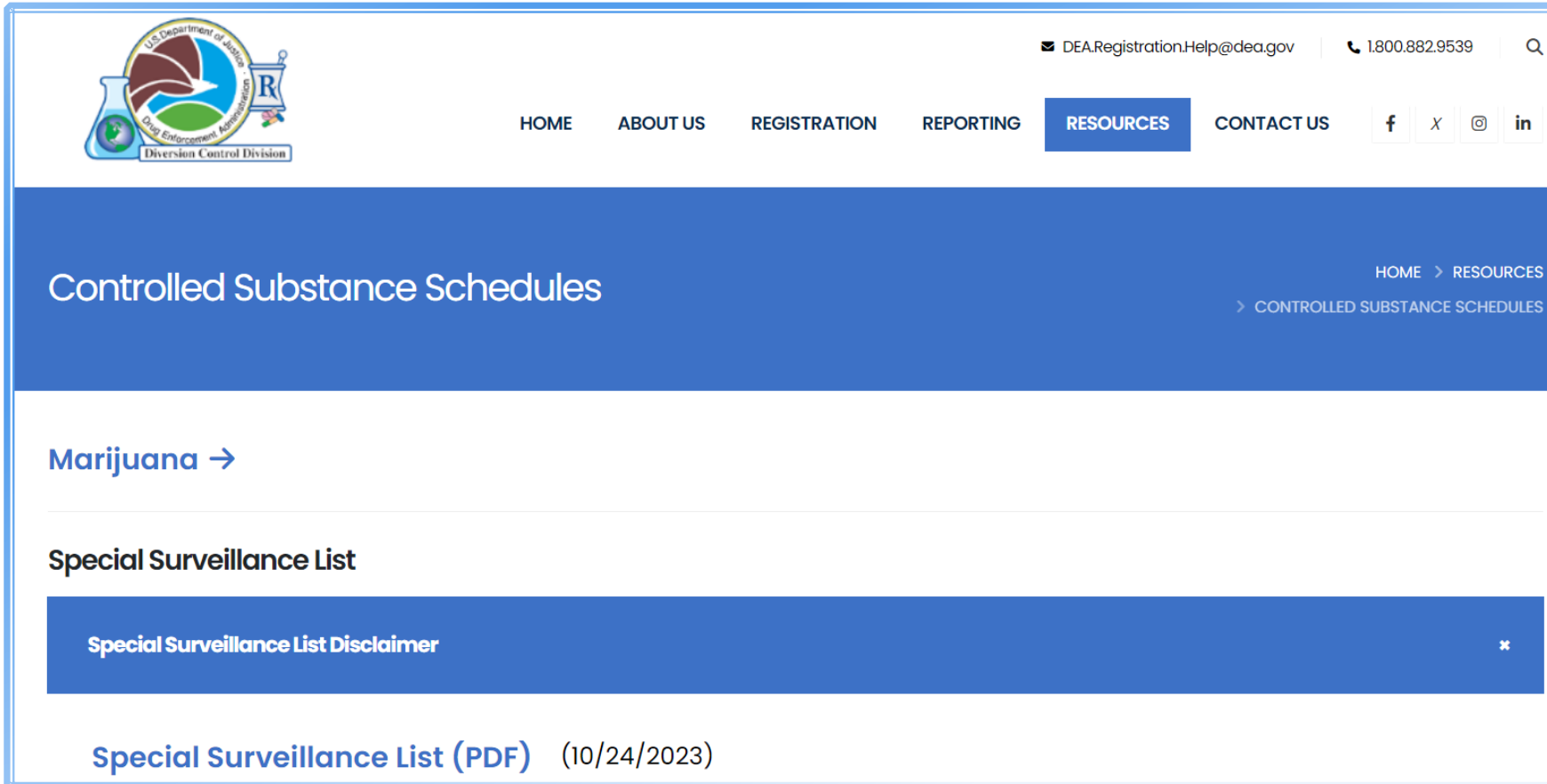
(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this subchapter or subchapter II, with reckless disregard for the illegal uses to which such a laboratory supply will be put; civil penalties for the distribution of a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, if that distribution was made with reckless disregard for the illegal uses to which such laboratory supply will be put. the maximum penalty is **\$470,640**.

"laboratory supply" means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals.

DEA – Diversion Control Division Website



<https://www.deadiversion.usdoj.gov/>



The screenshot shows the homepage of the DEA Diversion Control Division website. The header includes the DEA logo, contact information (DEA.Registration.Help@dea.gov, 1.800.882.9539), and a search bar. The navigation menu has links for HOME, ABOUT US, REGISTRATION, REPORTING, RESOURCES (highlighted), and CONTACT US. Social media icons for Facebook, X, Instagram, and LinkedIn are also present. The main content area features a blue banner with the text "Controlled Substance Schedules" and a breadcrumb trail: HOME > RESOURCES > CONTROLLED SUBSTANCE SCHEDULES. Below the banner, there is a link for "Marijuana →" and a section titled "Special Surveillance List". A blue box contains the text "Special Surveillance List Disclaimer" with a close button (x). At the bottom, there is a link for "Special Surveillance List (PDF) (10/24/2023)".

DEA.Registration.Help@dea.gov 1.800.882.9539

HOME ABOUT US REGISTRATION REPORTING **RESOURCES** CONTACT US

Controlled Substance Schedules

HOME > RESOURCES > CONTROLLED SUBSTANCE SCHEDULES

Marijuana →

Special Surveillance List

Special Surveillance List Disclaimer

Special Surveillance List (PDF) (10/24/2023)





- **Exempt chemical mixtures (21 CFR § 1310.12-13)**
- Exempt anabolic steroid products (21 CFR § 1308.33)
- **Exempt chemical preparations (21 CFR § 1308.23)**
- Exempt prescription products (21 CFR § 1308.31)



Exempt Chemical Mixtures



- Application **must** contain all information required
 - listed in 21 CFR § 1310.13(c)
- **Applicant** must demonstrate that
 - The mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance; and
 - The listed chemical or chemicals contained in the chemical mixture cannot be readily recovered
- Administrator may modify any part of the criteria for exemption
 - Issue and publish a Notice of Proposed Rulemaking in the Federal Register
 - Interested persons may file written comments or objections to the proposal
 - After consideration, the Administrator shall publish a final order in the Federal Register





- Requirements found in 21 CFR § 1308.23 and 1308.24
 - The Administrator may exempt a chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational or special research purposes and not for general administration to a human being or other animal, if the preparation either
 1. Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse
 2. Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion or concentration, that the preparation or mixture does not present any potential for abuse.



Exempt Chemical Preparations



- Exempt chemical preparation application process is documented in 21 CFR § 1308.23(b-d)
- Application must contain **all** information required
- If the application is accepted for filing, the Administrator shall issue and publish in the Federal Register the order on the application
 - Any interested person can file written comments on or objections to the order within 60 days of publication in the Federal Register



Scientific and Technical Support



- Drug and Chemical Evaluation Section
 - Drug and Chemical Information, Scheduling Actions, Exempted Lists
 - Bulk Chemical Manufacturer Reports
 - Control Status Determinations
- Resources found on Diversion Control Division Website (www.deadiversion.usdoj.gov)
 - Drug and Chemical Information Sheets
 - Lists of Controlled Substances
 - Exempted Lists
 - Exempt anabolic steroids
 - Exempt chemical preparations and mixtures
 - Exempted prescription products
 - Federal Register Notices





Contact

If you have any questions or inquiries,
please contact us at:

Drug & Chemical Evaluation Section

DPE@DEA.GOV

<https://www.dea.gov/>

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<https://www.deadiversion.usdoj.gov/>



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL DIVISION