



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-1282]

Designation of Phenethyl Halides as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing the control of phenethyl halides as list I chemicals under the Controlled Substances Act (CSA). Phenethyl halides are important to the illicit manufacture of fentanyl, as well as fentanyl analogues, and fentanyl-related substances as they are often used in synthetic routes to manufacture these substances. Further, in the respective synthetic routes in which they are used to manufacture fentanyl, fentanyl analogues, and fentanyl-related substances, various phenethyl halides, such as phenethyl bromide and phenethyl chloride, can be substituted for each other. If finalized, the proposed rule would subject handlers of phenethyl halides to the chemical regulatory provisions of the CSA and its implementing regulations. This proposed rulemaking does not establish a threshold for domestic and international transactions of phenethyl halides. As such, all transactions of phenethyl halides regardless of size or concentration, shall be regulated and would be subject to control under the CSA.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. 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*. 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.

- *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to Docket No. DEA-1282.

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

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found in the docket for this rulemaking at www.regulations.gov.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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>, unless reasonable cause is given. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked “CONTAINS CONFIDENTIAL INFORMATION” and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked “TO BE PUBLICLY POSTED” and must have all claimed PII and business information already redacted. DEA will post only the redacted comment on <https://www.regulations.gov> for public inspection. DEA generally will not redact additional information contained in the comment marked “TO BE PUBLICLY POSTED.” The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and a plain language summary of this notice of proposed rulemaking are available at <https://www.regulations.gov>.

Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General to specify, by regulation, chemicals as list I chemicals.¹ The Attorney General has delegated her authority to designate list I chemicals to the Administrator of DEA (Administrator).² A “list I

¹ 21 U.S.C. 802(34).

² 28 CFR 0.100(b).

chemical” is defined as “a chemical that is used in manufacturing a controlled substance in violation of [the CSA] and is important to the manufacture of the controlled substances.”³

The current list of all listed chemicals is published at 21 CFR 1310.02. DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the *Federal Register* following a published notice of proposed rulemaking with at least 30 days for public comments.

Background

The clandestine manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances remains extremely concerning as the distribution of these substances continue to drive drug-related overdose deaths in the United States. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950s. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. However, due to its desirable pharmacological effects, fentanyl can be used outside of its approved medical purposes. Opioid dependent individuals can use fentanyl as a substitute for heroin, oxycodone, or other opioids. Therefore, though fentanyl has an accepted medical use in the United States, it is controlled as a schedule II controlled substance due to its high potential for abuse.⁴

Moreover, there are a substantial number of fentanyl analogues⁵ and fentanyl-related substances⁶ that are being distributed on the illicit drug market despite DEA’s recent actions placing them under control of the CSA as schedule I controlled substances.⁷ Illicit

³ 21 U.S.C. 802(34).

⁴ 21 U.S.C. 812(c) Schedule II(b)(6); 21 CFR 1308.12(c)(9). On July 16, 2025, Congress enacted the HALT Fentanyl Act, Pub. L. 119-26, which, among other things, permanently places fentanyl-related substances as a class into schedule I of the CSA.

⁵ Schedules of Controlled Substances: Temporary Placement of Seven Fentanyl-Related Substances in Schedule I, 83 FR 4580 (Feb. 1, 2018).

⁶ Schedules of Controlled Substances: Temporary Placement of Fentanyl-Related Substances in Schedule I, 83 FR 5188 (Feb. 6, 2018).

⁷ Schedules of Controlled Substances: Placement of 10 Specific Fentanyl-Related Substances in Schedule I, 86 FR 22113 (Apr. 27, 2021).

manufacturers of fentanyl, fentanyl analogues, and fentanyl-related substances attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls in order to manufacture these substances. This strategy allows for the synthesis of a variety of fentanyl analogues and fentanyl-related substances by making slight modifications to the core fentanyl structure while maintaining the same synthetic methodology used to synthesize fentanyl, fentanyl analogues, and fentanyl-related substances.

The unlawful trafficking of fentanyl, fentanyl analogues, and fentanyl-related substances in the United States continues to pose an imminent hazard to public safety. Since 2012, fentanyl has shown a dramatic increase in the illicit drug supply as a single substance, in mixtures with other illicit drugs (*e.g.*, heroin, cocaine, and methamphetamine), and in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.⁸

DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl, fentanyl analogues, and fentanyl-related substances in the United States in recent years. According to the Centers for Disease Control and Prevention (CDC), opioids, mainly synthetic opioids (which includes fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,⁹ drug-induced overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019, to 56,516 in 2020, to 70,601 in 2021, and to 73,838 in 2022, with only a slight decrease to 72,776 in 2023, and a further decrease to 47,735 in 2024. Based on provisional data, the predicted number of drug overdose deaths involving synthetic opioids (excluding methadone) in the United States for the 12 months ending October 2025 is 39,649

⁸ United Nations Office on Drugs and Crime, Global SMART Update Volume 17, March 2017. https://www.unodc.org/documents/scientific/Global_SMART_Update_17_web.pdf.

⁹ Centers for Disease Control and Prevention, National Center for Health Statistics. National Vital Statistics System, Provisional Mortality on CDC WONDER Online Database. Data are from the final Multiple Cause of Death Files, 2018-2024, and from provisional data for years 2025 and later, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at <http://wonder.cdc.gov/mcd-icd10-provisional.html> on March 18, 2026.

individuals, or approximately 55.4 percent of all drug-induced overdose deaths for that time period.¹⁰ Overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),¹¹ reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2016, as shown in Table 1 (*2025 data still being reported).

Table 1. Annual Reports of Fentanyl and Select Fentanyl Analogues and Fentanyl-Related Substances Identified in Drug Encounters.

Year	2016	2017	2018	2019	2020	2021	2022	2023	2024	*2025
Annual Fentanyl Reports	37,158	61,648	90,014	108,225	126,404	166,651	177,227	183,009	154,015	89,003
Annual Reports of select fentanyl analogues and fentanyl-related substances	7,624	22,072	16,121	20,932	8,005	26,691	30,978	21,511	19,000	7.616

Role of Phenethyl Halides in the Synthesis of Fentanyl

¹⁰ Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2026. Accessed at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> on March 18, 2026.

¹¹ The National Forensic Laboratory Information System (NFLIS-Drug) is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, State and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332 (December 12, 2011). NFLIS-Drug data was queried on January 8, 2026; *2025 data is still reporting.

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, these substances can only be manufactured through synthetic organic chemistry. Synthetic organic chemistry is the process in which a new organic molecule is created through a series of chemical reactions, which involve precursor chemicals. Through chemical reactions using precursor chemicals, chemical structures can be modified in a desired fashion. These chemical reaction sequences, also known as synthetic pathways, are designed to create a desired substance. Several synthetic pathways to fentanyl, fentanyl analogues, and fentanyl-related substances have been identified in clandestine laboratory settings; these include the original “Janssen method,” the “Siegfried method,” and the “Gupta method.” In response to the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances using these methods, DEA controlled *N*-phenethyl-4-piperidone (NPP),¹² *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), *N*-phenylpiperidin-4-amine (4-anilinopiperidine; including its amides and carbamates),¹³ and 4-piperidone (piperidin-4-one)¹⁴ as list I chemicals, and 4-anilino-*N*-phenethylpiperidine (ANPP)¹⁵ and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)¹⁶ as schedule II immediate precursors under the CSA.

Phenethyl Halides

Phenethyl halides serve as precursors in the synthesis of fentanyl, its analogues, and fentanyl-related substances. Various phenethyl halides have been documented in the scientific literature and in reported clandestine seizures. Examples of these include phenethyl bromide and phenethyl chloride. The original published synthetic pathway to

¹² Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I Chemical, 72 FR 20039 (Apr. 23, 2007).

¹³ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (Apr. 15, 2020).

¹⁴ Designation of 4-Piperidone as a List I Chemical, 88 FR 21902 (Apr. 12, 2023).

¹⁵ Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

¹⁶ Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 85 FR 21320 (Apr. 17, 2020).

fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl¹⁷ and schedule II immediate precursor norfentanyl.¹⁸ In this synthetic route, benzylfentanyl is converted to norfentanyl. Norfentanyl is reacted with phenethyl chloride (also known as 2-chloroethyl benzene) to complete the synthesis of fentanyl. This synthetic route can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

In the Siegfried method, phenethyl bromide (also known as 2-bromoethyl benzene) is reacted with 4-piperidone, a list I chemical under the CSA, to produce NPP, another list I chemical, which is further converted to ANPP,¹⁹ the schedule II immediate precursor in the production of fentanyl using this method. One additional step completes the synthesis of fentanyl. This synthetic route can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl, one of which is known as the Gupta method. In this synthetic route, 4-piperidone is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,²⁰ which serves as an alternative to NPP for the synthesis of ANPP, albeit through a different synthetic route. 4-Anilinopiperidine is reacted with phenethyl bromide to produce ANPP, which is then converted to the schedule II controlled substance fentanyl. This synthetic route can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Phenethyl halides are attractive to illicit manufacturers due to the lack of regulations on these chemicals; they are readily available from chemical suppliers. Additionally, these substances, (*i.e.*, phenethyl fluoride, phenethyl chloride, phenethyl bromide, phenethyl

¹⁷ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

¹⁸ Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 85 FR 21320 (April 17, 2020).

¹⁹ Control of Immediate Precursor Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance, 75 FR 37295 (June 29, 2010).

²⁰ Designation of Benzylfentanyl and 4-Anilinopiperidine, Precursor Chemicals Used in the Illicit Manufacture of Fentanyl, as List I Chemicals, 85 FR 20822 (April 15, 2020).

iodide) are closely related and may be substituted for each other in many of the known synthetic routes. These synthetic routes can be easily used, and modified, in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

Information Gathered by DEA Concerning Phenethyl Halides

On October 28, 2024, DEA published in the *Federal Register* an Advance Notice of Proposed Rulemaking (ANPRM)²¹ in anticipation of proposing to designate phenethyl bromide, and related halides and sulfonates as list I chemicals. The ANPRM invited interested persons to submit information related to current uses of phenethyl bromide, and related halides and sulfonates (other than for the synthesis of fentanyl), in order to properly determine the effect such a proposed action would have on legitimate industry.

DEA solicited input from all potentially affected parties regarding: (1) the types of legitimate industries using phenethyl bromide, and related halides and sulfonates; (2) the legitimate uses, legitimate needs, and quantities produced, used, and distributed of phenethyl bromide, and related halides and sulfonates; (3) the size of the domestic market for phenethyl bromide, and related halides and sulfonates, if any; (4) the number of manufacturers of phenethyl bromide, and related halides and sulfonates; (5) the number of distributors of phenethyl bromide, and related halides and sulfonates; (6) the level of import and export of phenethyl bromide, and related halides and sulfonates; (7) the potential burden that controlling phenethyl bromide, and related halides and sulfonates, as a list I chemical may have on any legitimate industry and trade; (8) the potential number of individuals/firms that may be adversely affected by such regulatory controls (particularly with respect to the impact on small businesses); and (9) any other information on the manner of manufacturing, distribution, consumption, storage, disposal, and uses of phenethyl bromide, and related halides and sulfonates, by industry and others. DEA invited all interested parties to provide any information on any legitimate uses of phenethyl bromide, and related halides and

²¹ Possible Control of Phenethyl Bromide as a List I Chemical, 89 FR 85459 (Oct. 24, 2024).

sulfonates, in industry, commerce, academia, research and development, or other applications. DEA sought both quantitative and qualitative data.

Comments

DEA received three responses to the ANPRM. The comments stated support for, and against, the control of phenethyl bromide and/or related substances.

Comment: One comment was in support of the control of phenethyl bromide and other phenethyl halides but was vigorously opposed to the control of phenethyl sulfonates. The comment stated that it was unaware of other uses in industry except to synthesize fentanyl and other phenethyl-amides.

DEA Response: DEA agrees with the comment to control phenethyl bromide and other phenethyl halides. The opposition stated in this comment to the control of phenethyl sulfonates is outside the scope of this proposed rule as those substances are not being proposed for control.

Comment: The second comment was against the control of phenethyl bromide due to its importance in the synthesis of certain medications and study of new therapeutic compounds. The comment also noted the versatility of phenethyl bromide in a number of legitimate scientific and industrial applications. It further argued that overregulating individual chemicals fails to address the broader strategies employed by illicit manufacturers.

DEA Response: DEA appreciates the commenter's concern for the use of these chemicals in the synthesis of certain medications and study of new therapeutic compounds and application in scientific and industrial applications. DEA is aware that phenethyl halides may be used as an intermediate in several processes, including, but not limited to, pharmaceutical (including fentanyl manufacturing), scientific, and industrial applications. Designating phenethyl halides as list I chemicals does not preclude the use of phenethyl halides for end users (i.e., those using them as an intermediate chemical or in chemical synthesis). DEA registration for list I chemicals is only for those who are manufacturing, distributing, importing, or exporting

list I chemicals. It is not required for those doing synthesis, unless they are also participating in one of the aforementioned activities that require registration. Therefore, unless the user is also manufacturing, distributing, importing, or exporting phenethyl halides, the proposed action will not affect industries that may be using phenethyl halides as an intermediate in synthesis. Any potential burdens on industry are outweighed by the public health and public safety benefits of listing phenethyl halides.

With regard to the portion of the comment stating that overregulating individual chemicals fails to address the broader strategies employed by illicit manufacturers, DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and believes this rule will help control the illicit manufacture of fentanyl.

Comment: The third comment was in favor of regulating phenethyl bromide if it meets the requirements, and it also recommended regulating the online sales of this substance to mitigate access and distribution and prevent further manufacturing of fentanyl and fentanyl analogous substances.

DEA Response: DEA agrees with the comment favoring regulation of phenethyl bromide.

With regard to the recommendation to regulate online sales to mitigate access and distribution and prevent further manufacturing of fentanyl and fentanyl analogous substances, the proposed rule, if finalized, will regulate, in addition to manufacturing, the distribution, import, and export of phenethyl halides. As such, DEA believes the proposed controls will help mitigate the access and illegal distribution of these substances to manufacture fentanyl and analogous substances.

Proposed Designation of Phenethyl Halides as List I Chemicals

The CSA, specifically 21 U.S.C. 802(34), and its implementing regulations at 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, additional precursor or essential chemicals as listed chemicals if they are used in the manufacture of controlled substances in violation of the CSA. Recent law enforcement

encounters indicate phenethyl halides are being used in the illicit manufacture of the schedule II controlled substance fentanyl. This proposed rule would regulate phenethyl halides as list I chemicals because DEA finds that phenethyl halides are used in the illicit manufacture of the controlled substance fentanyl, fentanyl analogues, and fentanyl related substances and are important to the manufacture of these substances because they can be used, and substituted for each other, in various synthetic pathways which are used in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl related substances.

Chemical Mixtures of Phenethyl Halides

This rulemaking also proposes that chemical mixtures containing phenethyl halides would not be exempt from regulatory requirements at any concentration, unless a manufacturer submits to DEA an application for exemption of such chemical mixture, DEA accepts the application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13 (exemption of chemical mixtures by application). The control of chemical mixtures containing any amount of phenethyl halides is necessary to prevent the extraction, isolation, and use of phenethyl halides in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl related substances. This rule proposes the modification of the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of phenethyl halides are subject to CSA chemical control provisions.

Application Process for Exemption of Chemical Mixtures

DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations.²² Manufacturers may apply for an automatic exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d). Pursuant to 21 CFR 1310.13(a), DEA may grant an exemption of a chemical mixture, by publishing a final rule in the *Federal Register*, if DEA determines that: 1) the

²² 21 CFR 1310.13 specifies that this chemical mixture is a chemical mixture consisting of two or more chemical components, at least one of which is a list I or list II chemical. *See also* 21 CFR 1300.02 (defining the term “chemical mixture”).

mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and 2) the listed chemical or chemicals cannot be readily recovered.

Requirements for Handling List I Chemicals

If finalized as proposed, the designation of phenethyl halides as list I chemicals would subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Upon publication of a final rule, persons potentially handling phenethyl halides, including regulated chemical mixtures containing phenethyl halides, would be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling of, phenethyl halides, including chemical mixtures containing phenethyl halides, or proposes to engage in the manufacture, distribution, importation, or exportation of phenethyl halides, including chemical mixtures containing phenethyl halides, must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of list I chemicals.²³ Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.²⁴

DEA notes that under the CSA, “warehousemen” are not required to register and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment. Under DEA implementing regulations, the warehouse in question

²³ 21 CFR 1309.21.

²⁴ 21 U.S.C. 822(e)(1) (separate registration requirements pertaining to manufacturing or distributing a list I chemical); 21 CFR 1309.23(a).

must receive the list I chemical from a DEA registrant and shall only distribute the list I chemical back to the DEA registrant and registered location from which it was received.²⁵

A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such.

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting phenethyl halides or a chemical mixture containing phenethyl halides would become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirements to immediately complete and submit an application for registration, and for DEA to immediately issue registrations for those activities. Therefore, to allow any continued legitimate commerce in phenethyl halides or a chemical mixture containing phenethyl halides, DEA is proposing to establish in 21 CFR 1310.09, a temporary exemption from the registration requirement for persons desiring to engage in activities with phenethyl halides or a chemical mixture containing phenethyl halides, provided that DEA receives a properly completed application for registration or application for exemption of a chemical mixture under 21 CFR 1310.13 on or before 30 days after publication of a final rule implementing regulations regarding phenethyl halides. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of the final rule. This is necessary because a delay in regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

²⁵ See 21 CFR 1309.23(b)(1).

Additionally, the temporary exemption for registration does not suspend applicable federal criminal laws relating to phenethyl halides, nor does it supersede State or local laws or regulations. All handlers of phenethyl halides must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to phenethyl halides pursuant to 21 U.S.C. 830 and in accordance with 21 CFR 1310.04 and 1310.05. Pursuant to 21 CFR 1310.04, a record must be kept for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical will be required to submit manufacturing, inventory, and use data on an annual basis.²⁶ Existing standard industry reports containing the required information are acceptable, provided the information is separate or readily retrievable from the report.

The CSA and its implementing regulations require that each regulated person must report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of subchapter I of the CSA. In addition, regulated persons must report any proposed regulated transaction with a person whose description or other identifying characteristics DEA has previously furnished to the regulated person, any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier.²⁷

²⁶ 21 CFR 1310.05(d).

²⁷ 21 U.S.C. 830(b); 21 CFR 1310.05(a) and (b).

3. *Importation and Exportation.* All importation and exportation of phenethyl halides or a chemical mixture containing phenethyl halides would need to comply with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants would be required to provide effective controls against theft and diversion of list I chemicals in accordance with 21 CFR 1309.71-1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.²⁸

6. *Liability.* Any activity involving phenethyl halides not authorized by, or in violation of, the CSA, would be unlawful, and would subject the person to administrative, civil, and/or criminal action.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294 (Regulatory Review)

DEA has determined that this rulemaking is not a “significant regulatory action” under section 3(f) of Executive Order (E.O.) 12866, Regulatory Planning and Review. Accordingly, this proposed rule has not been submitted to the Office of Management and Budget for review. This proposed rule has been drafted and reviewed in accordance with E.O. 12866, “Regulatory Planning and Review,” section 1(b), Principles of Regulation and E.O. 13563, “Improving Regulation and Regulatory Review,” section 1(b), General Principles of Regulation.” DEA scheduling actions are not subject to either E.O. 14192,

²⁸ 21 U.S.C. 880.

Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

DEA is proposing the control of phenethyl halides as list I chemicals under the CSA. DEA finds that phenethyl halides are used in and important to the illicit manufacture of the controlled substances fentanyl, fentanyl analogues, and fentanyl-related substances. Phenethyl halides may be used as replacements for each other in various synthetic pathways to make fentanyl, its analogues, and related substances. If finalized, the proposed rule would subject handlers of phenethyl halides to the chemical regulatory provisions of the CSA and its implementing regulations. This proposed rulemaking does not establish a threshold for domestic and international transactions of phenethyl halides. As such, all transactions of phenethyl halides, regardless of size, shall be regulated. In addition, chemical mixtures containing phenethyl halides are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of phenethyl halides shall be regulated pursuant to the CSA. If finalized as proposed, phenethyl halides will be subject to all of the regulatory control and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals.

Phenethyl halides are used for the legitimate manufacturing of pharmaceutical fentanyl as well as clandestinely synthesized illicit fentanyl. DEA has searched information in the public domain for legitimate uses of phenethyl halides and has documented that phenethyl halides may be used as an intermediary chemical in several industries, including the production of fentanyl. Any manufacturer, distributor, importer, or exporter of phenethyl halides for the production of legitimate pharmaceutical fentanyl who are not already registered with DEA, if they exist at all, would incur costs if this proposed rule is finalized. Entities who currently use phenethyl halides for the legitimate manufacturing of

pharmaceutical fentanyl should be registered with DEA. DEA welcomes any comments related to the uses of phenethyl halides in the legitimate marketplace.

The primary costs associated with this proposed rule would be the annual registration fee for list I chemicals (\$3,699 for manufacturers and \$1,850 for distributors, importers, and exporters). However, any manufacturer that handles phenethyl halides for legitimate pharmaceutical fentanyl production should already be registered with DEA and have all security and other handling processes in place which result in minimal cost to those entities.

DEA has identified 120 domestic suppliers of phenethyl halides based on an internal search of the CAS SciFinder chemical compound database. Thirteen suppliers of phenethyl halides are already registered to handle list I chemicals per DEA's registration system. The remaining suppliers of each of the phenethyl halides are not registered with DEA to handle list I chemicals. It is difficult to estimate the quantity of phenethyl halides these suppliers distribute. It is also common for chemical distributors to have items in their catalogs while not actually having any realized sales. If this proposed rule is finalized, these suppliers are expected to choose the least costly option, and stop selling minimal quantities, if any, of phenethyl halides, rather than incur the registration cost.

In summary, DEA conducted a qualitative analysis of this proposed rule. DEA believes this proposed action, if finalized, will minimize the diversion of phenethyl halides. DEA believes the market for phenethyl halides for the legitimate manufacturing of pharmaceutical fentanyl is minimal. Additionally, any entity that uses phenethyl halides for legitimate pharmaceutical fentanyl production would be already registered with DEA and have all security and other handling processes in place which results in minimal cost to those entities. Therefore, any potential cost as a result of this regulation is minimal.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 Civil Justice Reform to eliminate drafting errors and ambiguity,

minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. This proposed rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601-612, has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

As discussed above, if finalized as proposed, phenethyl halides and chemical mixtures containing phenethyl halides will be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. If finalized, it will affect all business activities that handle phenethyl halides including manufacturers, distributors, importers, and exporters. As aforementioned, DEA identified 120 domestic suppliers of which 89 percent (107) are not registered with DEA to handle list I chemicals. All non-registered entities will be affected by this rule. Because DEA does not know the size of these entities, DEA conservatively assumes they are small entities based on the Small Business Administration classification for Other Chemical and Allied Products Merchant Wholesalers (NAICS classification code

424690); entities in this industry are considered small entities if they employ less than 175 employees.²⁹

The primary cost associated with this rule is the registration cost. Phenethyl halides may be used as an intermediary in various industries, including the manufacturing of fentanyl. Any entity that currently manufactures, distributes, imports, or exports phenethyl halides for pharmaceutical and industrial purposes would already be registered with DEA and have all security and other handling processes in place which result in minimal cost. However, this rule would only impose regulations on those who manufacture, distribute, import, or export phenethyl halides and not end users who are using the chemical as an intermediate. Additionally, entities may submit an application, and request approval for exemption of their chemical mixture containing phenethyl halides in accordance with 21 CFR 1310.13 (exemption of chemical mixtures by application) or through meeting the requirements stated in 21 CFR 1310.12(d) (automatic exemptions).

DEA believes the sales of the non-registered suppliers are minimal based on the number of comments from the ANPRM. Also, it is common for chemical distributors to have items in their catalog while not actually having any realized sales. Therefore, DEA estimates the cost of this rule on any affected small entity is minimal. DEA welcomes any public comments regarding this estimate.

Lastly, per the Statistics of U.S. Businesses annual data tables, there are 5,307 small entities under 424690 Other Chemical and Allied Products Merchant Wholesalers.³⁰ The number of small entities affected by this proposed rule is 2.02 percent of all the small businesses in this industry.³¹ Based on these factors, DEA projects that this rule, if

²⁹ U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, <https://www.sba.gov/document/support-table-size-standards>

³⁰ 2021 SUSB Annual Data Tables by Establishment Industry, <https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html>, accessed: 03/11/2025

³¹ Assuming all of the 107 non-registered suppliers are small businesses, the percent of small businesses affected by this rule is $107/5,307 = 2.02\%$

promulgated, will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the “Regulatory Flexibility Act” section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. . . .” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act of 1995

This action does not impose any new or revised “collection[s] of information” as defined by the Paperwork Reduction Act of 1995, 44 U.S.C. 3502(3). This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR part 1310

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1310 as follows:

**PART 1310— RECORDS AND REPORTS OF LISTED CHEMICALS AND
CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN
MACHINES**

1. The authority citation for 21 CFR part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. In § 1310.02, add paragraph (a)(43) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

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* * * * *	
(43) Phenethyl halides (i.e. phenethyl bromide, phenethyl chloride, phenethyl iodide, and phenethyl fluoride)	8338

* * * * *

3. In § 1310.04:

- a. Redesignate paragraphs (g)(1)(xv), (g)(1)(xvi), (g)(xvii), (g)(1)(xviii), (g)(1)(xix), (g)(1)(xx), (g)(1)(xxi), and (g)(1)(xxii) as paragraphs (g)(1)(xvi), (g)(1)(xvii), (g)(1)(xviii), (g)(1)(xix), (g)(1)(xx), (g)(1)(xxi), (g)(1)(xxii), and (g)(1)(xxiii), respectively; and
- b. Add new paragraphs (g)(1)(xv) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(xv) Phenethyl halides (i.e. phenethyl bromide, phenethyl chloride, phenethyl iodide, and phenethyl fluoride)

* * * * *

4. In § 1310.09 add new paragraph (v) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(v)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export phenethyl halides, including

regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing phenethyl halides pursuant to § 1310.13 on or before 30 days after the publication of a rule finalizing this action. The exemption would remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing phenethyl halides whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons would remain in effect until DEA takes final action on their registration application.

* * * * *

5. Section 1310.12 is amended by adding in alphabetical order in the table in paragraph (c) an entry for phenethyl halides, to read as follows:

* * * * *

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

DEA chemical code number	Concentration	Special conditions
List I Chemicals		

Phenethyl halides (i.e. phenethyl bromide, phenethyl chloride, phenethyl iodide, and phenethyl fluoride)	8338	Not exempt at any concentration	Chemical mixtures containing any amount of phenethyl halides (i.e. phenethyl bromide, phenethyl chloride, phenethyl iodide, and phenethyl fluoride) are not exempt.

* * * * *			

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on June 30, 2026, by Administrator Terrance Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Leslie Mayer
Federal Register Liaison Officer
Drug Enforcement Administration

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