(adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This proposed rule would not impose a new collection of information under the Paperwork Reduction Act of 1995.[13] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. 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 1308

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

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (f)(8) through (13) as (f)(9) through (14); and

■ b. Add a new paragraph (f)(8).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

*	*	*	*	*	*	*
(8) 4-Fluoroamphetamine (4–FA, 1-(4-fluorophenyl)propan-2-amine)						1476
*	*	*	*	*	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on May 27, 2025, by Acting Administrator Robert J. Murphy. 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–09988 Filed 6–2–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1189]

Designation of Propionyl Chloride as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing the control of propionyl chloride as a list I chemical under the Controlled Substances Act (CSA). The Drug Enforcement Administration finds that propionyl chloride is used in the illicit manufacture of the controlled substances fentanyl, fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances. In the respective synthetic pathways in which it is used to manufacture those substances, it is a replacement for propionic anhydride, which is currently a list I chemical. If finalized, the proposed rule would subject handlers of propionyl chloride 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 propionyl chloride. As such, all transactions of propionyl chloride, regardless of size, shall be regulated. In addition, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of propionyl chloride shall be regulated pursuant to the CSA. Although no automatic exemption is available, manufacturers may submit an application for exemption.

DATES: Comments must be submitted electronically or postmarked on or before July 3, 2025. 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–1189'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration 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 *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. 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,

[13] 44 U.S.C. 3501–3521.

8701 Morrissette 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–1189.

FOR FURTHER INFORMATION CONTACT: 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 rule may be found in the docket for this rulemaking at *www.regulations.gov.*

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *http://www.regulations.gov.* Such information includes personal or business identifiers (such as name, address, state or Federal identifiers, etc.) voluntarily submitted by the commenter. Generally, all information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously. The Freedom of Information Act applies to all comments received.

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 confidential PII and business information already redacted. DEA will post only the redacted comment on *http://www.regulations.gov* for public inspection.

For easy reference, an electronic copy of this document and supplemental information to this proposed scheduling action are available at *http://www.regulations.gov.*

Legal Authority

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, chemicals as list I chemicals.[1] A ''list I chemical'' is a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substance.[2] The current list of all listed chemicals is published at 21 CFR 1310.02. Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator). 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 (NPRM) 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 illicit fentanyl, fentanyl analogues, and fentanyl-related substances continues 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. Yet, due to its pharmacological effects, fentanyl can be used as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals. Therefore, despite its currently accepted medical use in treatment in the United States, DEA controls fentanyl as a schedule II controlled substance due to its high potential for abuse and the possibility that abuse may lead to severe psychological or physical dependence.[3] Moreover, there are a substantial number of fentanyl analogues and fentanyl-related substances that are being distributed on the illicit drug market despite DEA's actions adding them as schedule I controlled substances. Illicit manufacturers attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls in order to manufacture fentanyl, fentanyl analogues, and fentanyl-related 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 the 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 (*i.e.,* heroin, cocaine, and methamphetamine), and in forms that mimic pharmaceutical preparations including prescription opiates.[4]

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 include fentanyl), are predominantly responsible for drug overdose deaths in recent years. According to CDC WONDER,[5] 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 73,838 in 2022. 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 March 2024 is 70,972 individuals, or approximately 70 percent of all drug-induced overdose deaths for that time period.[6] The increase in overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl, fentanyl analogues, and fentanyl-related

[1] 21 U.S.C. 802(34).

[2] *Id.*

[3] 21 U.S.C. 812(c) Schedule II(b)(6) and 21 CFR 1308.12(c).

[4] National Drug Threat Assessment 2024, Drug Enforcement Administration, May 2024.

[5] 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, 2018–2022, and from provisional data for years 2022–2024, 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 August 16, 2024.

[6] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2024. Accessed at *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm* on August 16, 2024.

substances. According to the National Forensic Laboratory Information System (NFLIS-Drug),[7] reports from forensic laboratories of drug items containing fentanyl, fentanyl analogues, and fentanyl-related substances increased dramatically since 2014, as shown in Table 1.

TABLE 1—ANNUAL REPORTS OF FENTANYL AND SELECT FENTANYL ANALOGUES AND FENTANYL-RELATED SUBSTANCES IDENTIFIED IN DRUG ENCOUNTERS

Year	2014	2015	2016	2017	2018	2019	2020	2021	2022
Annual Fentanyl Reports	5,554	15,461	37,155	61,644	89,974	108,138	126,042	165,486	168,768
Annual Reports of select fentanyl analogues and fentanyl-related substances	78	2,317	7,624	21,981	16,177	20,918	7,804	26,468	29,919

Role of Propionyl Chloride in the Synthesis of Fentanyl

Fentanyl, fentanyl analogues, and fentanyl-related substances are not naturally occurring substances. As such, the manufacture of these substances requires them to be produced 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, the chemical structures of precursor chemicals are 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);[8] *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts;[9] *N*-phenylpiperidin-4-amine (4-anilinopiperidine) including its amides, halides, carbamates, salts, and any combination thereof;[10] and 4-piperidone (piperidin-4-one) including its acetals, amides, carbamates, salts, and salts of acetals, amides, and carbamates, and any combination thereof[11] as list I chemicals. DEA also controls 4-anilino-*N*-phenethylpiperidine (ANPP)[12] and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl)[13] as schedule II immediate precursors under the CSA.

Propionyl Chloride

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the list I chemical benzylfentanyl and schedule II immediate precursor norfentanyl. In this synthetic pathway, benzylfentanyl, a list I chemical under the CSA,[14] is synthesized by reacting propionyl chloride with 4-anilino-1-benzylpiperidine, which is then converted to norfentanyl, the schedule II immediate precursor in this synthetic pathway.[15] Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances. Propionyl chloride also serves as a precursor chemical in the Siegfried method. In this synthetic pathway, propionyl chloride is reacted with ANPP,[16] the schedule II immediate precursor in the Siegfried method, to complete the synthesis of fentanyl. This synthetic pathway 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 pathway, 4-piperidone, a list I chemical under the CSA, is used to synthesize 4-anilinopiperidine, another list I chemical under the CSA,[17] which serves as an alternative precursor chemical to NPP, a list I chemical, in the synthesis of ANPP, a schedule II immediate precursor albeit through a different synthetic process. The resulting ANPP is reacted with propionyl chloride to manufacture the schedule II controlled substance, fentanyl. This synthetic pathway can also be easily modified to produce fentanyl analogues and fentanyl-related substances.

Propionyl chloride is attractive to illicit manufacturers because there is a lack of regulations on this chemical, it is readily available from chemical suppliers, and it can be easily used in many known synthetic pathways used in the illicit manufacture of fentanyl, fentanyl analogues, and fentanyl-related substances.

Information Gathered by DEA Concerning Propionyl Chloride

On October 12, 2023, DEA published in the **Federal Register** an Advance Notice of Proposed Rulemaking (ANPRM)[18] in anticipation of proposing to designate propionyl chloride as a list I chemical. The ANPRM invited interested persons to submit information related to current uses of propionyl chloride (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 propionyl chloride; (2) the legitimate uses, legitimate needs and quantity

[7] 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 December 14, 2023.

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

[9] *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).

[10] *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).); See Also *Designation of Halides of 4-Anilinopiperidine as List 1 Chemicals,* 88 FR 74352 (Oct. 31, 2023).

[11] *Designation of 4-Piperidone as a List I Chemical,* 88 FR 21902–21910 (Apr. 12, 2023).

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

[13] *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).

[14] See footnote 10.

[15] See footnote 13.

[16] See footnote 12.

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

[18] *Propionyl Chloride,* 88 FR 70610 (Oct. 12, 2023).

produced, used, and distributed of propionyl chloride; (3) the size of the domestic market for propionyl chloride; (4) the number of manufacturers of propionyl chloride; (5) the number of distributors of propionyl chloride; (6) the level of import and export of propionyl chloride; (7) the potential burden that controlling propionyl chloride 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 propionyl chloride by industry and others. DEA invited all interested parties to provide any information on any legitimate uses of propionyl chloride in industry, commerce, academia, research and development, or other applications. DEA sought both quantitative and qualitative data.

Comments

DEA received six responses to the ANPRM. Three of the comments were in support of the control of propionyl chloride as a list I chemical, while three comments offered potential problems with controlling propionyl chloride.

Relevant to solicitations (1) and (2), three commenters stated that propionyl chloride has potential use as a reagent for chemical synthesis processes, including in the natural product syntheses of N-deoxymilitarinone A and torrubiellone B, potential pharmaceutical development, resin/materials development, and agricultural chemicals. One of the commenters stated that it may have uses for the medical field, without providing additional detail. While one of the comments provided patent numbers and a published letter to support the existence of these potential uses, there were no details allowing DEA to identify the existence or extent of the actual use of propionyl chloride for these purposes.

Relevant to solicitation (7), two commenters stated that controlling propionyl chloride as a list I chemical is likely to have a burden on legitimate industry and trade in that it will make the chemical more expensive and difficult to access for chemical and pharmaceutical research labs and will ''impact researchers greatly.'' A third commenter stated that distributors, manufacturers, importers, and exporters of propionyl would be required to pay DEA registration fees if propionyl chloride is placed in list I. Another commenter, however, stated that it may primarily be used by ''personnel who would already possess any documentation needed to obtain it.''

Relevant to solicitation (8), one commenter stated that PubChem lists 43 vendors currently offering to supply propionyl chloride.

Regulation of Propionyl Chloride as a List I Chemical

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 propionyl chloride is being used in the illicit manufacture of the schedule II controlled substance fentanyl. This proposed rule would regulate propionyl chloride as a list I chemical because DEA finds that propionyl chloride is used in the illicit manufacture of the controlled substance fentanyl, and is important to the manufacture of the controlled substance fentanyl because it can be used as a replacement for the list I chemical propionic anhydride in its respective synthetic pathways which are used in the illicit manufacture of fentanyl.

Chemical Mixtures of Propionyl Chloride

This proposed rulemaking, if finalized, would specify that chemical mixtures containing propionyl chloride would not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a propionyl chloride manufacturer and the application is reviewed and accepted by DEA under 21 CFR 1310.13. The control of chemical mixtures containing any amount of propionyl chloride is necessary to prevent the extraction, isolation, and use of propionyl chloride in the illicit manufacture of fentanyl. This proposed rule would modify the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of propionyl chloride are subject to the CSA chemical control provisions.

Exemption by Application Process

DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations.[19] Under the application process, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical cannot be readily recovered.[20]

Requirements for Handling List I Chemicals

If this rule is finalized as proposed, propionyl chloride 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. Upon publication of a final rule, persons potentially handling propionyl chloride, including regulated chemical mixtures containing propionyl chloride, will be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who manufactures, distributes, imports, or exports propionyl chloride, including chemical mixtures containing propionyl chloride, or proposes to engage in the manufacture, distribution, importation, or exportation of propionyl chloride, including chemical mixtures containing propionyl chloride, 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. 21 CFR 1309.21. 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. 21 U.S.C. 822(e)(1) and 21 CFR 1309.23(a).

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 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. A warehouse that distributes list I chemicals to persons other than the registrant and registered location from

[19] 21 CFR 1310.13.

[20] 21 CFR U.S.C. 802(39)(A)(vi).

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 propionyl chloride or a chemical mixture containing propionyl chloride 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 propionyl chloride or a chemical mixture containing propionyl chloride, 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 propionyl chloride or a chemical mixture containing propionyl chloride, 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 propionyl chloride. 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.

Additionally, the temporary exemption for registration does not suspend applicable federal criminal laws relating to propionyl chloride, nor does it supersede State or local laws or regulations. All handlers of propionyl chloride 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 propionyl chloride 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. 21 CFR 1310.05(d). 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. 21 U.S.C. 830(b) and 21 CFR 1310.05(a) and (b).

3. *Importation and Exportation.* All importation and exportation of propionyl chloride or a chemical mixture containing propionyl chloride would need to be done in compliance 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. 21 U.S.C. 880.

6. *Liability.* Any activity involving propionyl chloride 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, 1356, and 14192 (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 E.O. 14192, ''Unleashing Prosperity Through Deregulation.''

DEA is proposing the control of propionyl chloride as a list I chemical under the CSA. DEA finds that propionyl chloride is used in the illicit manufacture of the controlled substances fentanyl, fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances. The replacement chemical for propionyl chloride in the respective pathways is already a list I chemical. If finalized, the proposed rule would subject handlers of propionyl chloride 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 propionyl chloride. As such, all transactions of propionyl chloride, regardless of size, shall be regulated. In addition, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of propionyl chloride shall be regulated pursuant to the CSA. If finalized as proposed, propionyl chloride 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.

DEA evaluated the cost of this proposed rule. Due to many unknowns, DEA is unable to provide an estimated cost of this proposed rule; however, DEA believes the cost will not be significant and will be far below the E.O. 12866 3(f)(1) threshold.

Propionyl chloride is 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 propionyl chloride and has not documented a legitimate commercial or industrial use for propionyl chloride other than as an intermediary chemical in the production of fentanyl. DEA welcomes any comments related to the uses of propionyl chloride 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). DEA has identified 20 domestic distributors of propionyl chloride. Three are already registered to handle list I chemicals, and this rule will not have impacts on their operations. The remaining distributors will need to register with DEA and employ security and handling processes to continue supplying propionyl chloride. For the nonregistered suppliers, it is difficult to estimate the amount of propionyl chloride that they distribute. It is also common for these chemical distributors to have items in their catalog while not actually having any material level of sales. Hence, DEA expects the quantities of propionyl chloride distributed by nonregistered distributors is much smaller compared to the registered distributors. If this proposed rule is finalized, these distributors are expected to choose the least cost option, and stop selling propionyl chloride, rather than incur the registration cost. DEA expects that the cost of foregone sales is small; and thus, the cost of this proposed rule is minimal. DEA welcomes any public comment regarding this estimate.

In summary, DEA conducted a qualitative analysis of this proposed rule. DEA believes any manufacturer or distributor that uses propionyl chloride for legitimate pharmaceutical fentanyl production already would be registered with DEA and have all security and other handling processes in place, such that this regulation would result 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 Acting 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, propionyl chloride and chemical mixtures containing propionyl chloride 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 propionyl chloride including manufacturers, distributors, importers, and exporters. DEA identified 20 domestic suppliers, 17 (85 percent) of which are not registered with DEA to handle list I chemicals. All non-registered entities will be affected by this rule and are small entities based on Small Business Administration classification for Other Chemical and Allied Products Merchant Wholesalers (NAICS classification code 424690).[21]

There are 8,804 small entities under 424690 Other Chemical and Allied Products Merchant Wholesalers.[22] The number of small entities affected by this proposed rule is 0.19 percent of all the small businesses in this industry.[23] Based on these factors, DEA projects that this rule, if 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).

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 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)(40) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

* * * * *

(40) Propionyl chloride 8337

* * * * *

■ 3. In § 1310.04:

■ a. Redesignate paragraphs (g)(1)(xviii) and (g)(1)(xix) as paragraphs (g)(1)(xix) and (g)(1)(xx), respectively; and

[21] U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, *https://www.sba.gov/sites/sbagov/files/2023-*.

[22] 2021 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html,* accessed: 1/9/2024.

[23] Assuming all of the 17 non-registered suppliers are small businesses, the percent of small businesses affected by this rule is 17/8,804 = 0.19%.

■ b. Add new paragraph (g)(1)(xviii) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(xviii) Propionyl chloride

* * * * *

■ 4. In § 1310.09 add paragraph (t) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(t)(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 propionyl chloride, 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 propionyl chloride 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 propionyl chloride 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. In 1310.12, amend the table in paragraph (c) by adding in alphabetical order an entry for ''propionyl chloride'' to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
* *	*	* *	* * * *
Propionyl chloride	8337	Not exempt at any concentration.	Chemical mixtures containing any amount of propionyl chloride are not exempt.
* *	*	* *	* * * *

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on May 25, 2025, by Acting Administrator Robert J. Murphy. 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–09983 Filed 6–2–25; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Chapter 1

RIN 2125–AG08

Incorporating Safety Into Federal-Aid Programs and Projects

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Termination of rulemaking.

SUMMARY: FHWA terminates its rulemaking titled ''Incorporating Safety Into Federal-aid Programs and Projects.'' FHWA will proceed to formally terminate the rule from FHWA's upcoming Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions (''Unified Agenda'').

DATES: June 3, 2025.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Ritter, Office of Safety, (202) 493–0019, *Robert.Ritter@dot.gov;* or Mr. David Serody, Office of the Chief Counsel, (202) 366–4241, *David.Serody@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document may be viewed online through the Federal eRulemaking portal at *www.regulations.gov.* The website is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov.*

Background

FHWA had initiated a rulemaking titled ''Incorporating Safety Into Federal-aid Programs and Projects'' Regulation Identifier Number (RIN) 2125–AG08 to establish new regulations pertaining to integrating safety across Federal-aid highway programs. This rulemaking project was listed on FHWA's Unified Agenda; however, no Notice of Proposed Rulemaking was published in the **Federal Register**.