significance of these protections for customer assets.

Segregating or separating a firm's proprietary funds from customer funds is a critical element in protecting not only customers, but also the broader financial system. In the absence of the proposed risk management conditions and robust compliance with the same, conditions of financial distress could lead to preventable losses for customers or FCMs.[3]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1098]

Designation of Halides of 4-Anilinopiperidine as List I Chemicals

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing to modify the listing of the list I chemical, *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) (hereinafter referred to as 4-anilinopiperidine), to include halides of 4-anilinopiperidine. The current listing of 4-anilinopiperidine includes its amides, its carbamates, and its salts, as list I chemicals under the Controlled Substances Act. The Drug Enforcement Administration proposes the new listing to read as follows: *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible, as a list I chemical under the Controlled Substances Act.

DATES: Comments must be submitted electronically or postmarked on or before May 15, 2023. 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–1098'' 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 *https://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, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *https://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *https://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at *https://www.regulations.gov* for easy reference.

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 substances.[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 with at least 30 days for public comments.

Background

DEA previously found that 4-anilinopiperidine is used in the illicit manufacture of the controlled substance fentanyl (a schedule II substance under the CSA) and fentanyl analogues controlled in schedule I of the CSA, and is important to the manufacture of the controlled substance fentanyl and fentanyl analogues, because it cannot be replaced by other chemicals in its respective synthetic pathways that are used in the illicit manufacture of

[3] *Id.* (discussing Proposed Regulation § 39.13(j)(1)).

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

[2] *Id.*

fentanyl and fentanyl analogues.[3] On this basis, DEA previously specified that 4-anilinopiperidine is a list I chemical.[4] DEA has now found that halides of 4-anilinopiperidine are also used in the illicit manufacture of schedule I controlled substances, such as *para*-fluorofentanyl, *ortho*-fluorofentanyl, and *para*-chlorofentanyl. Accordingly, if finalized, this action would add halides of 4-anilinopiperidine to the prior listing of 4-anilinopiperidine and thereby subject handlers of halides of 4-anilinopiperidine to the chemical regulatory provisions of the CSA and its implementing regulations.

This proposed rule would not affect current handlers of 4-anilinopiperidine, including its amides, its carbamates, and its salts, as they would already be registered to handle 4-anilinopiperidine. This rulemaking does not establish a threshold for domestic and international transactions of halides of 4-anilinopiperidine. As such, all transactions of chemical mixtures containing halides of 4-anilinopiperidine will be regulated at any concentration and will be subject to control under the CSA.

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. Therefore, despite its accepted medical use in treatment in the United States, the DEA controls fentanyl as a schedule II controlled substance due to its high potential for abuse and dependence.[5]

The unlawful trafficking and distribution of fentanyl and fentanyl analogues 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 (*i.e.,* heroin, cocaine, and methamphetamine), or in forms that mimic pharmaceutical preparations, including prescription opiates and benzodiazepines.[6]

In recent years, the United States has experienced a significant increase in overdoses and overdose fatalities from fentanyl and fentanyl analogues. According to the Centers for Disease Control and Prevention (CDC), drug-induced overdose deaths involving synthetic opioids (excluding methadone) in the United States increased from 36,359 in 2019, to 56,516 in 2020, and to 70,589 in 2021 (provisional).[7] Further, CDC reports that opioids, mainly synthetic opioids (which includes fentanyl), are predominately responsible for drug overdose fatalities, as the drug overdose death data (109,247) predicted for the 12 month-ending March 2022, synthetic opioids were involved in about 67.3 percent of all drug-induced overdose deaths.[8]

The increase in overdose fatalities involving synthetic opioids coincides with a dramatic increase in law enforcement encounters of fentanyl and fentanyl analogues. According to the National Forensic Laboratory Information System (NFLIS-Drug),[9] reports from forensic laboratories of drug items containing fentanyl and several schedule I fentanyl analogues increased dramatically since 2014, as shown in Table 1.

TABLE 1—ANNUAL REPORTS OF FENTANYL AND HALOGENATED FENTANYL ANALOGUES IDENTIFIED IN DRUG ENCOUNTERS

Year	2014	2015	2016	2017	2018	2019	2020	2021
Fentanyl	5,553	15,461	37,144	61,628	89,890	107,928	124,773	156,629
Halogenated Fentanyl Analogues[10]	1	10	435	2,628	2,960	1,013	743	19,831

Role of 4-Anilinopiperidine in the Synthesis of Fentanyl and Fentanyl Analogues

Fentanyl and its analogues 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 and fentanyl analogues have been identified in clandestine laboratory settings, including the original ''Janssen method,'' the ''Siegfried method,'' and the ''Gupta method,'' which are further explained below.

In response to the illicit manufacture of fentanyl using these methods, DEA controlled *N*-phenethyl-4-piperidone (NPP);[11] *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), *N*-phenylpiperidin-4-amine (4-anilinopiperidine);[12] and proposed control of 4-piperidone[13] as list I chemicals. DEA also controlled 4-anilino-*N*-phenethylpiperidine

[3] 85 FR 20822 (Apr. 15, 2020).

[4] *Id.*

[5] 21 U.S.C. 812(c), Schedule II(b)(6); 21 CFR 1308.12(c).

[6] 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.*

[7] 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, 2018–2020, and from provisional data for years 2021–2022, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program. Accessed at *https://wonder.cdc.gov/mcd-icd10-provisional.html* on August 15, 2022.

[8] Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2021. Accessed at *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm* on May 5, 2022.

[9] 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 (Dec. 12, 2011). NFLIS-Drug data was queried on August 15, 2022.

[10] Halogenated fentanyl analogues reported to NFLIS-Drug include: *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-fluoroisobutyryl fentanyl, chlorofentanyl, fluoro furanyl fentanyl, fluorobutyryl fentanyl, fluorobutyryl/fluoroisobutyryl fentanyl, fluorofentanyl, fluoroisobutyryl fentanyl, *meta*-fluoro furanyl fentanyl, *ortho*-fluorobutyryl fentanyl, *ortho*-fluoroisobutyryl fentanyl, *ortho*-fluoro acrylfentanyl, *ortho*-fluoro furanyl fentanyl, *ortho*-fluorofentanyl, *ortho*-chlorofentanyl, *para*-chlorofentanyl, *para*-fluoro furanyl fentanyl, *para*-fluoro valeryl fentanyl, *para*-fluorobutyryl fentanyl, and *para*-fluorofentanyl.

[11] 72 FR 20039 (Apr. 23, 2007).

[12] 85 FR 20822 (Apr. 15, 2020).

[13] 87 FR 57852 (Sept. 22, 2022).

(ANPP) [14] and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) [15] as schedule II immediate precursors to fentanyl under the CSA.

In 2017, the United Nations Commission on Narcotic Drugs (CND) placed NPP and ANPP in Table I of the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 (1988 Convention) in response to the international reintroduction of fentanyl on the illicit drug market.[16] As such, member states of the United Nations were required to regulate these precursor chemicals at the national level. In addition, the People's Republic of China regulated NPP and ANPP on February 1, 2018.[17]

Following the international control of NPP and ANPP under the 1988 Convention, illicit fentanyl manufacturers moved to unregulated precursor chemicals. These included 4-anilinopiperidine, 1-boc-4–AP, and norfentanyl. In response, the CND placed 4-anilinopiperidine, 1-boc-4–AP, and norfentanyl in Table I of the 1988 Convention.[18]

On May 15, 2020, 4-anilinopiperidine became a list I chemical in the United States due to its role in the illicit manufacture of fentanyl.[19] Since that control action, DEA has observed an increase in identifications of certain fentanyl analogues by law enforcement and public health officials. Many of these fentanyl analogues contain a halogen atom on the aniline ring of its respective chemical structure. The presence of the halogen atom suggests that the fentanyl analogue was synthesized from a halogenated precursor chemical. Indeed, halogenated fentanyl precursors have been identified by law enforcement, such as *tert*-butyl 4-((4-fluorophenyl)amino)piperidine-1-carboxylate (*para*-fluoro 1-boc 4–AP). The chemical structure of this precursor defines it as a halide and carbamate of 4-anilinopiperidine. As such, it falls outside of the current definitions of a list I chemical, simply due to the presence of the fluorine (a halogen) atom. Although it is not regulated as a list I chemical, it can be used in the synthesis of fentanyl analogues, such as the schedule I substances *para*-fluorofentanyl, *para*-fluoroisobutyryl fentanyl, *para*-fluorobutyryl fentanyl, and *para*-fluoro furanyl fentanyl.

In addition, fentanyl analogues with both *meta*- and *ortho*-fluoro substitutions have been identified, such as *ortho*-fluorofuranyl fentanyl and *meta*-fluorofuranyl fentanyl. The identification of these substances suggests illicit fentanyl analogue manufacturers attempt to utilize unregulated precursor chemicals to evade law enforcement detection and precursor chemical controls. This strategy allows for the synthesis of a variety of fentanyl analogues by simply moving the fluorine atom around the aniline ring while maintaining the same synthetic methodology used to synthesize fentanyl and fentanyl analogues.

Likewise, other halogenated fentanyl analogues, such as those containing a chlorine atom, have been reported by forensic laboratories. According to NFLIS-Drug, *para*-chlorofentanyl and *ortho*-chlorofentanyl were reported for the first time in 2020. The identification of these substances suggests that illicit fentanyl analogue manufacturers utilize precursor chemicals containing a chlorine atom as an alternative to a fluorine atom in effort to evade law enforcement detection.

4-Anilinopiperidine

The original published synthetic pathway to fentanyl, known as the Janssen method, involves the two important precursors, benzylfentanyl and norfentanyl. 4-Piperidone,[20] a chemical proposed for list I control under the CSA, serves as a precursor chemical to benzylfentanyl, a list I chemical under the CSA,[21] which is converted to norfentanyl, the schedule II immediate precursor in this synthetic pathway. Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. Norfentanyl is controlled in schedule II of the CSA.[22]

Like the Janssen method, 4-piperidone serves as an early-stage precursor chemical in the Siegfried method. 4-Piperidone is a precursor to NPP, a known fentanyl precursor and list I chemical under the CSA,[23] in the Siegfried method. NPP is then converted to ANPP, the schedule II immediate precursor in this synthetic pathway. ANPP is then subjected to a simple one-step chemical reaction to complete the synthesis of fentanyl. ANPP is controlled as a schedule II immediate precursor under the CSA.[24]

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. 4-Anilinopiperidine, a list I chemical under the CSA,[25] is the key precursor in the Gupta method. 4-Anilinopiperidine serves as an alternative precursor chemical to NPP in the synthesis of ANPP, albeit through a different synthetic process. The resulting ANPP is then used as the immediate precursor chemical in the illicit manufacture of fentanyl.

Recent encounters of precursor chemicals related to 4-anilinopiperidine in chemical structure have occurred. These precursor chemicals contain a halogen atom on the aniline ring of 4-anilinopiperidine. Modifications have included the addition of a fluorine atom, a chlorine atom, or a bromine atom at different positions on the aniline ring of the 4-anilinopiperidine structure. The use of these halogenated 4-anilinopiperidine precursor chemicals in place of 4-anilinopiperidine has resulted in the illicit manufacturing of schedule I fentanyl analogues.

Halogenated 4-anilinopiperidines [26] are commercially available from both domestic and foreign suppliers. DEA is aware of at least 25 domestic suppliers and 14 foreign suppliers. Substituted versions of 4-anilinopiperidine, such as *para*-fluoro 1-boc-4-AP, are attractive to illicit manufacturers because they are readily available from chemical suppliers and the lack of regulations on these substituted precursor chemicals.

[14] 75 FR 37295 (Aug. 30, 2010).

[15] 85 FR 21320 (Apr. 17, 2020).

[16] 60th Session of the CND Dec/60/12 (ANPP) and Dec/60/13 (NPP).

[17] *https://www.dea.gov/press-release/2018/01/05/china-announces-scheduling-controls-two-fentanyl-precursor-chemicals.* Accessed March 9, 2022.

[18] In a letter dated May 27, 2022, the United Nations Office on Drugs and Crime, in accordance with Article 12, paragraph 6 of the 1988 Convention, informed the Permanent Mission of the United States of America to the United Nations (Vienna) that the CND decided to place the chemical 4–AP in Table I of the 1988 Convention (CND Dec/65/4) and the chemical 1-boc-4–AP in Table I of the 1988 Convention (CND Dec/65/5) at its 65th Session on March 16, 2022.

[19] 85 FR 20822 (April 15, 2020).

[20] 87 FR 57852 (Sept. 22, 2022).

[21] 85 FR 20822 (Apr. 15, 2020).

[22] 85 FR 21320 (Apr. 17, 2020).

[23] 72 FR 20039 (Apr. 23, 2007).

[24] 75 FR 37295 (Aug. 30, 2010).

[25] 85 FR 20822 (Apr. 15, 2020).

[26] Chemicals included the folowing: *ortho*-fluoro 4-AP, *ortho*-chloro 4-AP, *ortho*-bromo 4-AP, *meta*-fluoro 4-AP, *meta*-chloro 4-AP, *meta*-bromo 4-AP, *para*-fluoro 4-AP, *para*-chloro 4-AP, *para*-bromo 4-AP, *ortho*-fluoro 1-boc-4-AP, *ortho*-chloro 1-boc-4-AP, *ortho*-bromo 1-boc-4-AP, *meta*-fluoro 1-boc-4-AP, *meta*-chloro 1-boc-4-AP, *meta*-bromo 1-boc-4-AP, *para*-fluoro 1-boc-4–AP, *para*-chloro 1-boc-4-AP, and *para*-bromo 1-boc-4-AP.

para-Fluoro 1-boc-4-AP has been identified in law enforcement encounters in the United States. According to NFLIS-Drug, beginning in 2020, there have been at least nine reports of *para*-fluoro 1-boc-4-AP from forensic laboratories in the United States. A query of DEA's STARLiMS [27] database provided 16 reports of *para*-fluoro 1-boc-4-AP from analyses conducted on submitted drug evidence by DEA forensic laboratories. Of these 16 reports, *para*-fluoro 1-boc-4-AP was the only substance reported in nine exhibits (totaling more than 29 kg), suggesting that these seizures were intended to be used as precursor chemicals in the synthesis of fentanyl analogues. Additionally, *para*-fluoro 1-boc-4-AP was reported in combination with *para*-fluorofentanyl in four of the seven exhibits containing a mixture of substances, suggesting that *para*-fluoro 1-boc-4-AP was a precursor chemical involved in the synthesis of *para*-fluorofentanyl, a schedule I substance under the CSA.

As of August 2022, in addition to domestic encounters, the International Narcotics Control Board of the United Nations reported two international transactions of *para*-fluoro 1-boc-4-AP through the Precursors Incident Communication System (PICS) [28] reporting system. These incidents reported to PICS totaled approximately 51 kg and had destinations located in North America.

These recent law enforcement encounters of *para*-fluoro 1-boc-4-AP coincide with the placement of NPP, ANPP, 4-anilinopiperidine, 1-boc-4-AP (*tert*-butyl 4-(phenylamino)piperidine-1-carboxylate), and norfentanyl in Table I of the 1988 Convention, the People's Republic of China regulating NPP and ANPP as of February 1, 2018, and the regulation of benzylfentanyl and proposed control of 4-piperidone as list I chemicals in the United States. The domestic encounters of *para*-fluoro 1-boc-4-AP at ports of entry indicate a change in precursors used in the illicit manufacture of fentanyl to substituted precursor chemicals used in the illicit manufacture of fentanyl analogues in efforts to evade international controls on NPP, ANPP, 4-anilinopiperidine, 1-boc-4-AP, and norfentanyl and additional controls on benzylfentanyl in the United States.

[27] On October 1, 2014, DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. STARLiMS data was queried on September 12, 2022.

[28] PICS is a platform that allows governments to exchange operational and investigative intelligence and to generate strategic intelligence on precursors trafficking. PICS reports were collected up to August 23, 2022.

Regulation of 4-Anilinopiperidine, Including Its Amides, Its Carbamates, Its Halides, Its Salts, and Any Combination Thereof, Whenever the Existence of Such Is Possible, 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 halides of 4-anilinopiperidine are being used in the illicit manufacture of schedule I fentanyl analogues. This proposed rule would modify the current regulations that regulate 4-anilinopiperidine, including its amides, its carbamates, and its salts to include halides of 4-anilinopiperidine. DEA finds that 4-anilinopiperidine, including its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible, is used in the illicit manufacture of controlled substances, such as fentanyl and fentanyl analogues, and is important to the manufacture of these substances because it cannot be replaced by other chemicals in their respective synthetic pathways that are used in the illicit manufacture of fentanyl and fentanyl analogues.

Chemical Mixtures of 4-Anilinopiperidine

This proposed rulemaking, if finalized, would modify the current regulations that regulate 4-anilinopiperidine, including its amides, its carbamates, and its salts to include halides of 4-anilinopiperidine. The regulations would specify that chemical mixtures containing halides of 4-anilinopiperidine would not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a manufacturer of halides of 4-anilinopiperidine and the application is reviewed and accepted by DEA under 21 CFR 1310.13 (Exemption by Application Process). The control of chemical mixtures containing any amount of halides of 4-anilinopiperidine is necessary to prevent the extraction, isolation, and use of halides of 4-anilinopiperidine in the illicit manufacture of schedule I fentanyl analogues. 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 4-anilinopiperidine, including its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible, 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.[29] 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.[30]

Requirements for Handling List I Chemicals

On May 15, 2020, DEA regulated 4-anilinopiperidine, including its amides, its carbamates, and its salts, as a list I chemical under the CSA. This proposed rule would expand the definitions of 4-anilinopiperidine to include its halides. Halides of 4-anilinopiperidine would become subject to the regulatory provisions of the CSA upon publication of a final rule. Chemicals that meet the current definition of 4-anilinopiperidine [31] have been, and continue to be, subject to the regulatory provisions of the CSA since May 15, 2020.

If this rule is finalized as proposed, halides of 4-anilinopiperidine 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, just as 4-anilinopiperidine, including its amides, its carbamates, and its salts are currently regulated. Upon publication of a final rule, persons potentially handling halides of 4-anilinopiperidine, including regulated chemical mixtures containing halides of 4-anilinopiperidine, will be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who manufactures, distributes, imports, or exports halides of 4-anilinopiperidine, including chemical mixtures containing halides of 4-anilinopiperidine, or

[29] 21 CFR 1310.13.

[30] 21 U.S.C. 802(39)(A)(vi).

[31] 85 FR 20822.

proposes to engage in the manufacture, distribution, importation, or exportation of halides of 4-anilinopiperidine, including chemical mixtures containing halides of 4-anilinopiperidine, 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.[32] 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.[33]

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 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 halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine 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 halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine, DEA is proposing to update the listing in 21 CFR 1310.09(p), to include the proposed updated definitions of 4-anilinopiperidine to include a temporary exemption from the registration requirement for persons desiring to engage in activities with the proposed updated definitions of halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine, 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 the proposed updated definitions of 4-anilinopiperidine. 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 halides of 4-anilinopiperidine, nor does it supersede State or local laws or regulations. All handlers of halides of 4-anilinopiperidine 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 halides of 4-anilinopiperidine pursuant to 21 U.S.C. 830 and in accordance with 21 CFR part 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.

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); 21 CFR 1310.05(a) and (b).

3. Importation and Exportation. All importation and exportation of halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine 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.[34]

6. Liability. Any activity involving halides of 4-anilinopiperidine not authorized by, or in violation of, the CSA, would be unlawful, and would subject the person to administrative, civil, and/or criminal action.

Solicitation for Information

As part of this proposed rulemaking, DEA is soliciting information on any possible legitimate uses of halides of 4-anilinopiperidine unrelated to fentanyl production (including industrial uses) in order to assess the potential economic impact of controlling halides of 4-anilinopiperidine as defined in this proposed rule. DEA has searched information in the public domain for legitimate uses of this chemical, and has not documented a legitimate commercial or industrial use for halides of 4-anilinopiperidine. DEA seeks, however, to document any unpublicized use(s) and other proprietary use(s) of halides of 4-anilinopiperidine that are not in the public domain. Therefore, DEA is soliciting comment on the uses of halides of 4-anilinopiperidine in the legitimate marketplace.

DEA is soliciting input from all potentially affected parties regarding: (1) The types of legitimate industries using halides of 4-anilinopiperidine; (2) the legitimate uses of halides of 4-anilinopiperidine, if any; (3) the size of the domestic market for halides of 4-anilinopiperidine; (4) the number of manufacturers of halides of 4-anilinopiperidine; (5) the number of

[32] 21 CFR 1309.21.

[33] 21 U.S.C. 822(e)(1); 21 CFR 1309.23(a).

[34] 21 U.S.C. 880.

distributors of halides of 4-anilinopiperidine; (6) the level of import and export of halides of 4-anilinopiperidine; (7) the potential burden these proposed regulatory controls of halides of 4-anilinopiperidine may have on any legitimate trade; (8) the potential number of individuals/firms that may be adversely affected by these proposed 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 halides of 4-anilinopiperidine by industry and others. DEA invites all interested parties to provide any information on any legitimate uses of halides of 4-anilinopiperidine in industry, commerce, academia, research and development, or other applications. DEA seeks both quantitative and qualitative data.

Handling of Confidential or Proprietary Information

Confidential or proprietary information may be submitted as part of a comment regarding this Notice of Proposed Rulemaking. Please see the ''POSTING OF PUBLIC COMMENTS'' section above for a discussion of the identification and redaction of confidential business information and personally identifying information.

Regulatory Analyses

Executive Orders 12866 and 13563, Regulatory Planning and Review, Improving and Regulation and Regulatory Review

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal Governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

A review of the 25 domestic suppliers of halides of 4-anilinopiperidine indicates that these entities are not registered with DEA to handle list I chemicals. These 25 suppliers are entities that do not also supply 4-anilinopiperidine as these entities would already be registered to handle list I chemicals since 4-anilinopiperidine is currently a list I chemical under the CSA. Therefore, the modified definitions of 4-anilinopiperidine in this proposed rule would potentially affect 25 entities. DEA anticipates that this proposed rule will impose minimal or no economic impact on affected entities; and thus, will not have a significant economic impact on any of the 25 affected small entities. Therefore, DEA concludes this proposed rule is not a significant regulatory action under E.O. 12866. If finalized as proposed, halides of 4-anilinopiperidine 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, just as 4-anilinopiperidine, including its amides, its carbamates, and its salts, is currently regulated. 4-Anilinopiperidine is a precursor chemical used in, and is important to, the illicit manufacture of the schedule II controlled substance fentanyl and schedule I fentanyl analogues. The distribution of illicitly manufactured fentanyl and fentanyl analogues has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years.

DEA has searched information in the public domain for any legitimate uses of halides of 4-anilinopiperidine, and has not documented a use for halides of 4-anilinopiperidine. DEA welcomes any public comment on these quantities and their economic significance.

DEA evaluated the costs and benefits of this proposed action.

Costs

DEA believes the market for halides of 4-anilinopiperidine for the legitimate manufacturing of pharmaceutical fentanyl is minimal because halides of 4-anilinopiperidine are not used to synthesize fentanyl or any schedule II fentanyl analogue currently used in medical practice. As stated above, DEA is not aware of any legitimate uses of halides of 4-anilinopiperidine. Any manufacturer, distributor, importer, or exporter of halides of 4-anilinopiperidine, if they exist at all, would incur costs if this proposed rule were finalized. The primary costs associated with this proposed rule would be the annual registration fees for list I chemicals ($3,699 for manufacturers and $1,850 for distributors, importers, and exporters). However, DEA believes that the cost will be minimal.

DEA has identified 25 domestic suppliers of halides of 4-anilinopiperidine. None of these 25 suppliers are registered to handle list I chemicals. It is difficult to estimate the quantity of distribution of halides of 4-anilinopiperidine by these suppliers. It is common for chemical distributors to have items in their catalog while not actually having any material level of sales. If this proposed rule is finalized, suppliers for the legitimate use of halides of 4-anilinopiperidine are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of halides of 4-anilinopiperidine, rather than incur the registration cost. Because DEA believes the quantities of halides of 4-anilinopiperidine supplied for the legitimate manufacturing of pharmaceutical fentanyl are minimal, DEA estimates that the cost of foregone sales is minimal; thus, the cost of this proposed rule is minimal. DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacturing and distribution of halides of 4-anilinopiperidine for the manufacturing of illicit fentanyl and fentanyl analogues. As a law enforcement organization and as a matter of principle, DEA believes considering the economic utility of facilitating the manufacture of illicit fentanyl would be improper.

Benefits

Controlling halides of 4-anilinopiperidine is expected to prevent, curtail, and limit the unlawful manufacture and distribution of fentanyl and fentanyl analogues. As a list I chemical, handling of halides of 4-anilinopiperidine would require registration with DEA and various controls and monitoring as required by the CSA. This proposed rule is also expected to assist preventing the

possible theft or diversion of halides of 4-anilinopiperidine from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing halides of 4-anilinopiperidine and selling them (as unregulated materials) through the internet and other channels, to individuals who may wish to acquire unregulated intermediary chemicals for the purpose of illicitly manufacturing fentanyl and fentanyl analogues.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this proposed action, if finalized, will minimize the diversion of halides of 4-anilinopiperidine. DEA believes the market for halides of 4-anilinopiperidine for the legitimate manufacturing of fentanyl or schedule II fentanyl analogues currently used in medical practice is minimal since halides of 4-anilinopiperidine are not used to synthesize fentanyl or any schedule II fentanyl analogue currently used in medical practice. 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 proposed 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, halides of 4-anilinopiperidine or a chemical mixture containing halides of 4-anilinopiperidine 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. Halides of 4-anilinopiperidine are precursor chemicals used in, and important to, the illicit manufacture of the schedule I fentanyl analogues. The distribution of illicitly manufactured fentanyl and fentanyl analogues has caused an unprecedented outbreak of thousands of fentanyl-related overdoses in the United States in recent years. DEA has not identified any legitimate industrial use for halides of 4-anilinopiperidine. Therefore, DEA believes the vast majority, if not all, of halides of 4-anilinopiperidine is used for the illicit manufacturing of schedule I fentanyl analogues. The primary costs associated with this proposed rule are the annual registration fees ($3,699 for manufacturers and $1,850 for distributors, importers, and exporters). DEA has identified 25 domestic suppliers of halides of 4-anilinopiperidineall of which are not registered with DEA to handle list I chemicals. All non-registered domestic suppliers are affected and are estimated to be small entities (based on Small Business Administration size standard for chemical distributors and Statistics of U.S. Business data).[35] It is impossible to know how much halides of 4-anilinopiperidine is distributed by these suppliers. It is common for chemical distributors to have items in their catalog while not actually having any material level of sales. Therefore, DEA estimates the cost of this proposed rule on any affected small entity is minimal. DEA welcomes any public comment regarding this estimate. Based on these factors, DEA projects that this proposed 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.

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, revise paragraph (a)(33) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(33) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible	8335

* * * * *

■ 3. In § 1310.04, revise paragraph (g)(1)(xiii) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(xiii) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-

[35] *https://www.sba.gov/sites/default/files/2018-07/NAICS%202017%20Table%20of%20Size%20Standards.pdf.*

piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible

* * * * *

■ 4. In § 1310.09, revise paragraph (p) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(p)(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 regulated *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible, 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 halides of 4-anilinopiperidine 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 *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible, 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 will remain in effect until DEA takes final action on their registration application.

* * * * *

■ 5. In § 1310.12, in the table in paragraph (c), revise the entry for *N*-phenylpiperidin-4-amine to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
* *	* *	*	*
N-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, its halides, its salts, and any combination thereof, whenever the existence of such is possible.	8335	Not exempt at any concentration.	Chemical mixtures containing any amount of 4-anilinopiperidine are not exempt.
* *	* *	*	*

* * * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on April 3, 2023, by Administrator Anne Milgram. 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 RegisterLiaison 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**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–07454 Filed 4–13–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 502, 556, and 558

RIN 3141–AA32

Definitions; Background Investigation for Primary Management Officials and Key Employees; Gaming Licenses for Primary Management Officials and Key Employees

AGENCY: National Indian Gaming Commission, Department of the Interior.

ACTION: Proposed rule.

SUMMARY: In 2022, the Commission issued a proposed rule seeking to amend the ''primary management official'' and ''key employee'' definitions; add definitions for ''Gaming Enterprise'' and ''Tribal Gaming Regulatory Authority'' (TGRA); and establish modern retention requirements for background investigations and licensing applications. The rule proposed vesting revocation hearing rights upon license issuance as well as in accord with tribal law, regulation or policy along with augmenting revocation decision notification and submission requirements. This revised proposed rule results from comments received. It permits tribes to designate and document other gaming enterprise employees as key employees and other employed gaming enterprise management officials as primary management officials, including TGRA personnel. Now such designations may occur by any documentary means. Updates to the key employee definition include custodians of gaming supplies and gaming operation employees authorized by the gaming operation for unescorted access to secure gaming areas, not vendors or other outside parties. The primary management official definition, however, now is narrower with the removal of individuals who have authority to