DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–497]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing the designation of *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (also known as benzylfentanyl), including its salts, and *N*-phenylpiperidin-4-amine (also known as 4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP) (hereinafter referred to as 4-anilinopiperidine), including its amides, its carbamates, and its salts, as list I chemicals under the Controlled Substances Act (CSA). DEA proposed control of benzylfentanyl and 4-anilinopiperidine due to their use in clandestine laboratories to illicitly manufacture the schedule II controlled substance fentanyl. This rulemaking finalizes the control of benzylfentanyl and 4-anilinopiperidine as list I chemicals.

DATES: This rulemaking will become effective on May 15, 2020. Persons seeking registration must apply on or before May 15, 2020 to continue their business pending final action by DEA on their application.

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SUPPLEMENTARY INFORMATION: DEA is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl. Therefore, on September 13, 2019, DEA published a Notice of Proposed Rulemaking (NPRM) to control the precursor chemicals benzylfentanyl and 4-anilinopiperdine as list I chemicals. 84 FR 48314. This rulemaking finalizes that NPRM.

This action subjects handlers of benzylfentanyl and 4-anilinopiperidine to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of benzylfentanyl or 4-anilinopiperidine. As such, all transactions involving benzylfentanyl or 4-anilinopiperidine are regulated, regardless of transaction size or quantity, and are subject to control under the CSA. In addition, chemical mixtures containing benzylfentanyl or 4-anilinopiperidine are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of benzylfentanyl or 4-anilinopiperidine are regulated pursuant to the CSA.

Legal Authority

The CSA gives the Attorney General the authority to specify, by regulation, chemicals as list I or list II chemicals. 21 U.S.C. 802(34) and (35). A ''list I chemical'' is a chemical that is used in manufacturing a controlled substance in violation of Title II of the CSA and is important to the manufacture of the controlled substance. 21 U.S.C. 802(34). A ''list II chemical'' is a chemical (other than a list I chemical) that is used in manufacturing a controlled substance in violation of Title II of the CSA. 21 U.S.C. 802(35). 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 and list II chemicals to the Administrator of the Drug Enforcement Administration.

Background

DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl. Fentanyl is a synthetic opioid and was first synthesized in Belgium in the late 1950's. Fentanyl is controlled in schedule II of the CSA due to its high potential for abuse and dependence, and accepted medical use in treatment in the United States. Fentanyl was introduced into medical practice and is approved for medical practitioners in the United States to prescribe lawfully for anesthesia and analgesia. Due to its pharmacological effects, fentanyl can serve as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals.

The unlawful trafficking of fentanyl 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), or in forms that mimic pharmaceutical preparations including prescription opiates and benzodiazepines.

DEA has noted a significant increase in overdoses and overdose fatalities from fentanyl in the United States in recent years. A recent report [1] from the Centers for Disease Control and Prevention (CDC) highlights this trend. According to this report, of the 41,430 drug overdose deaths occurring in the United States in 2011, 1,662 (4.0 percent) involved fentanyl.[2] Of the 63,632 drug overdose deaths in 2016, 18,335 (28.8 percent) involved fentanyl. This was the first time that fentanyl was reported in more drug related fatalities than heroin.

The increase of drug overdose deaths continued into 2017. According to the CDC,[3] there were 70,237 drug overdose deaths in the United States in 2017, an increase from the 63,632 overdose deaths recorded in 2016. Of the 70,237 overdose deaths in 2017, 47,600 (67.8 percent) involved an opioid. Deaths involving prescription opioids and heroin remained stable from 2016 to 2017; synthetic opioid overdose deaths (other than methadone), which include deaths involving fentanyl, increased 45.2 percent from 19,413 deaths in 2016 to 28,466 deaths in 2017.

The increase in overdose fatalities involving fentanyl coincides with a dramatic increase of law enforcement encounters of fentanyl. According to the National Forensic Laboratory Information System (NFLIS),[4] submissions to forensic laboratories that contained fentanyl increased exponentially beginning in 2012: 694 in 2012, 1,044 in 2013, 5,537 in 2014, 15,455 in 2015, 37,294 in 2016, 61,382 in 2017, and 70,453 in 2018.

Role of These Precursor Chemicals in the Synthesis of Fentanyl

Fentanyl is not a naturally occurring substance. As such, the manufacture of fentanyl requires it to be produced through synthetic organic chemistry. Synthetic organic chemistry is the process in which an organic molecule is created through a series of chemical reactions, which involve precursor

[1] Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011–2016. National Vital Statistics Reports; vol 67 no 9. Hyattsville, MD: National Center for Health Statistics, 2018.

[2] The reported data includes fentanyl, fentanyl metabolites, precursors, and analogs.

[3] Scholl L, Seth P, Kariisa M, Wilson N, Baldwin G. Drug and Opioid-Involved Overdose Deaths—United States, 2013–2017. MMWR Morb Mortal Wkly Rep 2019;67:1419–1427.

[4] The National Forensic Laboratory Information System (NFLIS) 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. NFLIS data was queried on March 26, 2019.

chemicals. In the early 2000's, a synthetic process, commonly known as the Siegfried method, was utilized to manufacture fentanyl in several domestic and foreign clandestine laboratories. 72 FR 20039. At that time, DEA had determined that two primary synthesis routes (*i.e.,* the Janssen method and the Siegfried method) were being used to produce fentanyl clandestinely, although it believed the Janssen synthesis route to be difficult to perform and beyond the rudimentary skills of most clandestine laboratory operators. The Siegfried synthetic route involves two important intermediates, *N*-phenethyl-4-piperidone (NPP) and 4-anilino-*N*-phenethylpiperidine (ANPP). DEA controlled NPP on April 23, 2007, as a list I chemical through an interim rule (72 FR 20039), which was finalized on July 25, 2008. 73 FR 43355. ANPP was controlled as a schedule II immediate precursor to fentanyl on August 30, 2010. 75 FR 37295.

In 2017, the United Nations Commission on Narcotic Drugs 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. As such, member states of the United Nations were required to control these precursor chemicals at the national level. In addition, the People's Republic of China controlled NPP and ANPP on February 1, 2018.

Recent law enforcement information indicates that illicit manufacturers of fentanyl may utilize synthetic routes other than the Siegfried method in response to international controls placed on NPP and ANPP. The Janssen method, previously thought to be beyond the skills of most clandestine laboratory operators, is now used with the precursor chemical benzylfentanyl, and other synthetic routes use the precursor chemical 4-anilinopiperidine. DEA is not aware of any legitimate uses of benzylfentanyl or 4-anilinopiperidine other than in the synthesis of fentanyl.

Benzylfentanyl

The original published synthetic pathway to fentanyl, known as the Janssen method, does not involve NPP or ANPP as a chemical precursor. This synthetic pathway involves the important precursors, benzylfentanyl and norfentanyl. Benzylfentanyl is converted to *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl), the immediate precursor in this synthetic pathway, in one chemical reaction. Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl.

According to DEA forensic laboratory data, the Janssen method was confirmed as the synthetic route used in 94 percent of 85 fentanyl drug exhibits that were evaluated to determine the synthetic route. These exhibits were seized in 2018. In addition, the number of law enforcement encounters of benzylfentanyl has increased in 2017 and 2018, which coincides with the international control that placed NPP and ANPP in Table I of the 1988 Convention in 2017.

According to NFLIS, there was one identification of benzylfentanyl in 2016; however, benzylfentanyl was identified in 195 reports in 2017 and 237 reports in 2018. Since DEA is not aware of any legitimate uses of benzylfentanyl other than potentially in the synthesis of fentanyl, it is believed that these law enforcement encounters indicate a change in the synthetic route to the Janssen method by some clandestine manufacturers in efforts to evade chemical regulations on NPP and ANPP.

DEA has determined that benzylfentanyl is commercially available from both domestic and foreign chemical suppliers. DEA is aware of at least five domestic suppliers and three foreign suppliers in China, two suppliers in Canada, and one supplier in the United Kingdom. Benzylfentanyl is attractive to illicit manufacturers due to the lack of chemical regulations on this substance, it is readily available from chemical suppliers, and it can be converted to the immediate precursor, norfentanyl, in a one-step chemical reaction.

4-Anilinopiperidine

In addition to the Janssen and Siegfried methods, clandestine manufacturers are using other methods to synthesize fentanyl. 4-Anilinopiperidine can serve as an alternative precursor chemical to NPP in the synthesis of ANPP, albeit through a different synthetic process. 4-Anilinopiperidine has been marketed as a replacement to ANPP as a precursor chemical used in the illicit manufacture of fentanyl by foreign chemical suppliers. This is believed to be in response to international controls placed on NPP and ANPP. Although marketed as a replacement for ANPP, DEA understands that 4-anilinopiperidine is not a direct replacement for ANPP in the synthesis of fentanyl. DEA is not aware of any legitimate uses of 4-anilinopiperidine other than potentially in the synthesis of fentanyl. In contrast to NPP, where two chemical reaction steps are required to synthesize ANPP, 4-anilinopiperidine can be converted to ANPP in a one-step chemical reaction. The resulting ANPP can then be used as the immediate precursor chemical in the illicit manufacture of the schedule II controlled substance, fentanyl. ANPP was controlled in schedule II of the CSA as of August 30, 2010 for this reason. 75 FR 37295 (June 29, 2010).

4-Anilinopiperidine has been imported and identified in law enforcement seizures in the United States. In addition to domestic encounters, DEA is aware of international encounters of 4-anilinopiperidine beginning as early as July 2018. The International Narcotics Control Board of the United Nations reported 32 international transactions of 4-anilinopiperidine through the International Operations on Novel Psychoactive Substances Communication System (IONICS) [5] reporting system. These identifications, totaling approximately 30 kg, were reported by Mexico as the destination country. In addition, 4-anilinopiperidine was identified at a clandestine laboratory located in Mexico, which was involved in the illicit manufacture of fentanyl.

These recent law enforcement encounters of 4-anilinopiperidine coincide with the placement of NPP and ANPP in Table I of the 1988 Convention, and the February 1, 2018, control of NPP and ANPP in the People's Republic of China. The international encounters of 4-anilinopiperidine at ports of entry in Mexico indicate a change in illicit fentanyl manufacturing methods in efforts to evade international controls on NPP and ANPP.

DEA determined that 4-anilinopiperidine is commercially available from both domestic and foreign chemical suppliers. DEA has identified 38 domestic suppliers and 28 foreign suppliers of 4-anilinopiperidine from Canada (3), China (11), Germany (3), Hong Kong (1), India (1), Latvia (1), Lithuania (1), Switzerland (2), and the United Kingdom (5). 4-Anilinopiperidine is attractive to illicit manufacturers due to the lack of chemical controls on this substance, it is readily available from chemical suppliers, and it can easily be converted to the schedule II immediate precursor, ANPP, which can subsequently be converted to fentanyl.

[5] IONICS is a free communication platform dedicated to real-time communication of incidents involving suspicious shipments, trafficking, manufacture or production of Novel Psychoactive Substances (NPS). IONICS reports were collected up to April 1, 2019.

Regulation of Benzylfentanyl, Including Its Salts and 4-Anilinopiperidine, Including Its Amides, Its Carbamates, and Its Salts, as List I Chemicals

The CSA, specifically 21 U.S.C. 802(34), 21 U.S.C. 802(35), 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 benzylfentanyl and 4-anilinopiperidine are being used in the illicit manufacture of the schedule II controlled substance fentanyl.

On September 13, 2019, DEA published an NPRM proposing control of benzylfentanyl and 4-anilinopiperidine as list I chemicals due to their use in clandestine laboratories to illicitly manufacture the schedule II controlled substance fentanyl. This rulemaking finalizes the control of benzylfentanyl and 4-anilinopiperidine as list I chemicals because DEA finds that benzylfentanyl and 4-anilinopiperidine are used in the manufacture of the controlled substance fentanyl, and are important to the manufacture of the controlled substance fentanyl because they cannot be replaced by other chemicals in their respective synthetic pathways in the manufacture of fentanyl.

Comments Received

As part of the NPRM published on September 13, 2019 (84 FR 48314), DEA specifically solicited comment on any possible legitimate uses of benzylfentanyl and 4-anilinopiperidine unrelated to fentanyl production (including industrial uses) in order to assess the potential commercial impact of controlling benzylfentanyl and 4-anilinopiperidine. DEA had searched information in the public domain for legitimate uses of these two chemicals, and had not documented a legitimate commercial use for benzylfentanyl or 4-anilinopiperidine other than as intermediary chemicals in the production of fentanyl. DEA sought, however, to document any unpublicized use(s) and other proprietary use(s) of benzylfentanyl and 4-anilinopiperidine that are not in the public domain. Therefore, DEA solicited comment on the uses of benzylfentanyl and 4-anilinopiperidine in the legitimate marketplace.

DEA solicited input from all potentially affected parties regarding: (1) The types of legitimate industries using benzylfentanyl and 4-anilinopiperidine; (2) the legitimate uses of benzylfentanyl and 4-anilinopiperidine, if any; (3) the size of the domestic market for benzylfentanyl and 4-anilinopiperidine; (4) the number of manufacturers of benzylfentanyl and 4-anilinopiperidine; (5) the number of distributors of benzylfentanyl and 4-anilinopiperidine; (6) the level of import and export of benzylfentanyl and 4-anilinopiperidine; (7) the potential burden these proposed regulatory controls of benzylfentanyl and 4-anilinopiperidine may have on any legitimate commercial activities; (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 benzylfentanyl and 4-anilinopiperidine by industry and others. DEA invited all interested parties to provide any information on any legitimate uses of benzylfentanyl and 4-anilinopiperidine in industry, commerce, academia, research and development, or other applications. DEA sought both quantitative and qualitative data. DEA did not receive any responses to these specific solicitations.

In response to the NPRM, DEA received four comments. Two commenters were in support of controlling benzylfentanyl and 4-anilinopiperidine as list I chemicals. One commenter expressed concern over a regulatory mechanism that would place benzylfentanyl and 4-anilinopiperidine in schedule I of the CSA. One commenter submitted a response that was outside the scope of the action.

Comment: One commenter stated that this rule will be an integral part of domestic regulation of illegal fentanyl by decreasing manufacture of illegal fentanyl. This commenter also expressed concern about the ease of obtaining, and importing illegal fentanyl and chemical precursors into the United States.

DEA response: DEA agrees that this rule is an important step in decreasing illicit fentanyl production and making it more difficult to obtain and import these chemical precursors into the United States. This rule provides law enforcement a tool to identify and investigate illicit fentanyl manufacturers. As list I chemicals, imports and exports of benzylfentanyl and 4-anilinopiperidine will be regulated per 21 CFR part 1313.

Comment: One commenter stated that benzylfentanyl and 4-anilinopiperidine must be regulated as list I chemicals to reduce illicit access to fentanyl. The commenter expressed concern about uncontrolled illicit production of fentanyl and the recent outcomes of fentanyl abuse in the United States.

DEA response: DEA agrees with the comment in support of controlling benzylfentanyl and 4-anilinopiperidine as list I chemicals. DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and believes this rule will help to control the illicit manufacture of fentanyl.

Comment: One commenter expressed concern about a regulatory mechanism that places benzylfentanyl and 4-anilinopiperidine in schedule I. The commenter proposed a separate regulatory avenue for precursors which submits them to scrutiny, study, and regulation in order to protect the public without resorting to the use of schedule I regulation. The commenter further stated that schedule I designations have a long history of hampering research and advancement of medicine in the United States.

DEA response: This rule does not place benzylfentanyl and 4-anilinopiperidine in schedule I of the CSA. The CSA currently provides a mechanism to regulate precursor chemicals separately, which is the authority utilized in this rule. 21 U.S.C. 802(34). Since benzylfentanyl and 4-anilinopiperidine are not subject to schedule I regulations, the comment is unrelated to this action. However, DEA supports and encourages legitimate research on schedule I controlled substances.

Comment: One commenter stated that controlling benzylfentanyl and 4-anilinopiperidine as list I chemicals is a bad idea and recommended keeping the government from micromanaging our economy and hobbling future production for emergencies. The commenter also stated that fentanyl gas can be used in hostage situations.

DEA response: DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and believes this rule will help to control the illicit manufacture of fentanyl. DEA believes that this rule will not have a significant impact on the economy or on legitimate manufacture of fentanyl. DEA also believes any potential cost as a result of this regulation is minimal. The comment regarding hostage situations is outside the scope of this rule.

Chemical Mixtures of Benzylfentanyl and 4-Anilinopiperidine

Under this rulemaking, chemical mixtures containing benzylfentanyl or 4-anilinopiperidine shall not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a benzylfentanyl or 4-anilinopiperidine manufacturer 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 benzylfentanyl or 4-anilinopiperidine is necessary to prevent the illicit extraction, isolation, and use of benzylfentanyl or 4-anilinopiperidine to manufacture fentanyl. This rule modifies the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of benzylfentanyl or 4-anilinopiperidine 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. 21 CFR 1310.13. 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 (*i.e.,* it meets the conditions in 21 U.S.C. 802(39)(A)(vi)).

Requirements for Handling List I Chemicals

This final rule subjects benzylfentanyl and 4-anilinopiperidine 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 the effective date of this final rule, persons handling benzylfentanyl or 4-anilinopiperidine, including regulated chemical mixtures containing benzylfentanyl or 4-anilinopiperidine, shall be required to comply with list I chemical regulations, including the following:

1. *Registration.* Any person who manufactures, distributes, imports, or exports benzylfentanyl or 4-anilinopiperidine, or proposes to engage in the manufacture, distribution, importation, or exportation of benzylfentanyl or 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.

Upon the effective date of this final rule, any person manufacturing, distributing, importing, or exporting benzylfentanyl or 4-anilinopiperidine, or a chemical mixture containing benzylfentanyl or 4-anilinopiperidine, will become subject to the registration requirement under the CSA. However, DEA recognizes that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in benzylfentanyl and 4-anilinopiperidine, DEA is establishing in 21 CFR 1310.09, a temporary exemption from the registration requirement for persons desiring to engage in activities with benzylfentanyl or 4-anilinopiperidine, provided that DEA receives a properly completed application for registration or exemption of a chemical mixture on or before May 15, 2020. 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 this 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 benzylfentanyl or 4-anilinopiperidine, nor does it supersede State or local laws or regulations. All handlers of benzylfentanyl or 4-anilinopiperidine must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to benzylfentanyl and 4-anilinopiperidine pursuant to 21 U.S.C. 830 and in accordance with 21 CFR part 1310. 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 must 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.

3. *Importation and Exportation.* All importation and exportation of benzylfentanyl or 4-anilinopiperidine must 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 must 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 benzylfentanyl or 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.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This final rulemaking, which adds benzylfentanyl and 4-anilinopiperidine as list I chemicals, was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 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 Executive Order. DEA has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f).

Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation.[6] In furtherance of this requirement, Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.[7] According to guidance provided by OMB, the requirements of Executive Order 13771 only apply to each new ''significant regulatory action that . . . imposes costs.'' [8] This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

This final rulemaking subjects benzylfentanyl and 4-anilinopiperidine to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. Benzylfentanyl and 4-anilinopiperidine are used in, and are important to, the illicit manufacture of the schedule II controlled substance fentanyl. The distribution of illicitly manufactured fentanyl 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 these two chemicals, and has not documented a use for benzylfentanyl or 4-anilinopiperidine other than as intermediary chemicals in the production of fentanyl. Based on the review of import and quota information for NPP, ANPP, and fentanyl, DEA believes the vast majority of, if not all, legitimate pharmaceutical fentanyl is produced via a synthetic route involving NPP and ANPP as intermediaries, not benzylfentanyl (and norfentanyl) or 4-anilinopiperidine. The quantities of NPP and ANPP indicated in import and quota documents generally correspond with the quantities of legitimate pharmaceutical fentanyl produced in the United States. Therefore, DEA concludes the vast majority of, if not all, benzylfentanyl or 4-anilinopiperidine is used for the manufacturing of illicit fentanyl.

DEA cannot rule out the possibility that minimal quantities of benzylfentanyl or 4-anilinopiperidine are used for the manufacturing of legitimate pharmaceutical fentanyl. However, if there are any quantities of benzylfentanyl or 4-anilinopiperidine used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant. DEA did not receive comment to the contrary.

DEA evaluated the costs and benefits of this action.

Costs

DEA believes the market for benzylfentanyl or 4-anilinopiperidine for the legitimate manufacturing of pharmaceutical fentanyl is minimal. As stated above, the only use for benzylfentanyl and 4-anilinopiperidine of which DEA is aware is as intermediaries for the manufacturing of fentanyl. Any manufacturer, distributor, importer, or exporter of benzylfentanyl or 4-anilinopiperidine for the production of legitimate pharmaceutical fentanyl, if they exist at all, will incur costs upon the effective date of this final rule. The primary costs associated with this rule would be the annual registration fees for scheduled drugs or list I chemicals ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). However, any manufacturer that uses benzylfentanyl or 4-anilinopiperidine for legitimate pharmaceutical fentanyl production would already be registered with DEA and have all security and other handling processes in place because of the controls already in place on fentanyl, resulting in minimal cost to those entities. While different forms of handling the scheduled substance versus the list I chemical (distribution of fentanyl vs exporting benzylfentanyl) could require a separate registration for the different handling of the substances, if an entity is already registered to handle, manufacture, import, or export a scheduled substance, the entity would not need an additional registration for the list I chemical, provided it is handling the list I chemical in the same manner that it is registered for with the scheduled substance, or as a coincident activity permitted by 21 CFR 1309.21. Even with the possibility of these additional registrations, DEA believes that the cost will be minimal.

DEA has identified 38 domestic suppliers of benzylfentanyl, 4-anilinopiperidine, or both. Only one is registered to handle list I chemicals, the remaining 37 are not registered with DEA to handle list I chemicals. It is difficult to estimate how much benzylfentanyl and 4-anilinopiperidine is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for NPP, ANPP, and fentanyl, where the quantities of NPP and ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical fentanyl manufacturing is minimal. Upon the effective date of this final rule, suppliers for the legitimate use of benzylfentanyl or 4-anilinopiperidine are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of benzylfentanyl or 4-anilinopiperidine, rather than incur the registration cost. Because DEA believes the quantities of benzylfentanyl or 4-anilinopiperidine supplied for the legitimate manufacturing of pharmaceutical fentanyl are minimal, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this rule is minimal. DEA requested public comment regarding this estimate; however, no public comment was received during the notice and comment period.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacturing and distribution of benzylfentanyl or 4-anilinopiperidine for the production of manufacturing illicit fentanyl. 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.

[6] Sec. 2(a).

[7] Sec. 2(c).

[8] OMB Guidance Implementing Executive Order 13771 titled ''Reducing Regulation and Controlling Regulatory Costs'' (April 5, 2017).

Benefits

Controlling benzylfentanyl and 4-anilinopiperidine is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substance, fentanyl. As list I chemicals, handling of benzylfentanyl and 4-anilinopiperidine requires registration with DEA and various controls and monitoring as required by the CSA. This rule is also expected to assist preventing the possible theft or diversion of benzylfentanyl and 4-anilinopiperidine from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing benzylfentanyl and 4-anilinopiperidine and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire unregulated intermediary chemicals for the purpose of manufacturing illicit fentanyl.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this action will minimize the diversion of benzylfentanyl and 4-anilinopiperidine. DEA believes the market for benzylfentanyl and 4-anilinopiperidine for the legitimate manufacturing of pharmaceutical fentanyl is minimal. Therefore, any potential cost as a result of this regulation is minimal.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 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 rulemaking does not have federalism implications warranting the application of Executive Order 13132. The 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 rule does not have tribal implications warranting the application of Executive Order 13175. This 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, benzylfentanyl and 4-anilinopiperidine shall 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 the effective date of this rulemaking. Benzylfentanyl and 4-anilinopiperidine are used in, and are important to, the illicit manufacture of the schedule II controlled substance fentanyl. The distribution of illicitly manufactured fentanyl 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 benzylfentanyl and 4-anilinopiperidine, other than their role as intermediary chemicals in the production of fentanyl. However, DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced via a synthetic route involving NPP and ANPP as intermediaries, not benzylfentanyl (and norfentanyl) or 4-anilinopiperidine. The review of import and quota information for fentanyl, ANPP, and NPP supports this belief. Therefore, DEA believes the vast majority, if not all, of benzylfentanyl or 4-anilinopiperidine is used for the illicit manufacturing of fentanyl. DEA did not receive comment to the contrary. The primary costs associated with this rule are the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters). Additionally, any manufacturer that uses benzylfentanyl or 4-anilinopiperidine for legitimate pharmaceutical fentanyl production would already be registered with DEA and have all security and other handling processes in place, resulting in minimal cost. DEA has identified 38 domestic suppliers of benzylfentanyl, 4-anilinopiperidine, or both, 37 of which are not registered with DEA to handle list I chemicals. All 37 non-registered domestic suppliers are affected, of which 35 (94.5%, based on Small Business Administration size standard for chemical distributors and Statistics of U.S. Business data) are estimated to be small entities. It is impossible to know how much benzylfentanyl or 4-anilinopiperidine is distributed by these suppliers. It is common for chemical distributors to have items on their catalog while not actually having any material level of sales. Based on the review of import and quota information for NPP, ANPP, and fentanyl, where the quantities of NPP and ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for legitimate pharmaceutical fentanyl manufacturing is minimal. DEA did not receive comment to the contrary. Therefore, DEA estimates the cost of this rule on any affected small entity is minimal. DEA did not receive public comment regarding this estimate. Based on these factors, DEA projects that this rule 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

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1310

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

For the reasons set out above, DEA amends 21 CFR part 1310 as follows:

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

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

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

■ 2. In § 1310.02 add paragraphs (a)(32) and (33) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

* * * * *

■ 3. In § 1310.04:

■ a. Redesignate paragraphs (g)(1)(viii) through (xi) as paragraphs (g)(1)(x) through (xiii), respectively;

■ b. Redesignate paragraph (g)(1)(vii) as paragraph (g)(1)(viii); and

■ c. Add new paragraphs (g)(1)(vii) and (ix).

The additions read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(vii) *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts

* * * * *

(ix) *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), its amides, its carbamates, and its salts

* * * * *

■ 4. In § 1310.09 add paragraphs (o) and (p) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(o)(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*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing benzylfentanyl pursuant to § 1310.13 on or before May 15, 2020. The exemption will 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*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts 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.

(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) and its amides, its carbamates, and its salts, including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing 4-anilinopiperidine pursuant to § 1310.13 on or before May 15, 2020. The exemption will 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) and its amides, its carbamates, and its salts 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, the Table of Concentration Limits in paragraph (c) is amended by adding entries for ''*N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl)'' and ''*N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP)'' in alphabetical order to read as follows:

§ 1310.12 Exempt chemical mixtures.

* * * * *

(c) * * *

TABLE OF CONCENTRATION LIMITS

	DEA chemical code No.	Concentration	Special conditions
* * *	*	* *	*
N-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl), including its salts.	8334	Not exempt at any concentration ...	Chemical mixtures containing any amount of benzylfentanyl are not exempt.
N-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine; 4–AP), including its amides, its carbamates, and its salts.	8335	Not exempt at any concentration ...	Chemical mixtures containing any amount of 4-anilinopiperidine are not exempt.
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Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–07064 Filed 4–14–20; 8:45 am]

BILLING CODE 4410–09–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe certain interest assumptions under the regulation for plans with valuation dates in May 2020. These interest assumptions are used for paying certain benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective May 1, 2020.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Regulatory Affairs Division, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005, 202–326–4400 ext. 3829. (TTY users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400, ext. 3829.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminated single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulation are also published on PBGC's website (*https://www.pbgc.gov*).

PBGC uses the interest assumptions in appendix B to part 4022 (''Lump Sum Interest Rates for PBGC Payments'') to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Because some private-sector pension plans use these interest rates to determine lump sum amounts payable to plan participants (if the resulting lump sum is larger than the amount required under section 417(e)(3) of the Internal Revenue Code and section 205(g)(3) of ERISA), these rates are also provided in appendix C to part 4022 (''Lump Sum Interest Rates for Private-Sector Payments'').

This final rule updates appendices B and C of the benefit payments regulation to provide the rates for May 2020 measurement dates.

The May 2020 lump sum interest assumptions will be 0.50 percent for the period during which a benefit is (or is assumed to be) in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for April 2020, these assumptions represent an increase of 0.50 percent in the immediate rate and are otherwise unchanged.

PBGC updates appendices B and C each month. PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to issue new interest assumptions promptly so that they are available for plans that rely on our publication of them each month to calculate lump sum benefit amounts.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during May 2020, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, rate set 319 is added at the end of the table to read as follows:

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *