(h) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail Rotor Blades.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–496]

Control of the Immediate Precursor Norfentanyl Used in the Illicit Manufacture of Fentanyl as a Schedule II Controlled Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is designating the precursor chemical, *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) as an immediate precursor for the schedule II controlled substance fentanyl. Furthermore, DEA is finalizing the control of norfentanyl as a schedule II substance under the Controlled Substances Act (CSA).

DATES: This rulemaking becomes effective May 18, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for 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 believes that the control of norfentanyl as a schedule II controlled substance is necessary to prevent its diversion as an immediate chemical intermediary for the illicit manufacture of fentanyl.

DEA is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl. Therefore, on September 17, 2019, DEA published a Notice of Proposed Rulemaking (NPRM) to designate the precursor chemical, *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl), as an immediate precursor of the schedule II controlled substance fentanyl under the definition set forth in 21 U.S.C. 802(23), and to control it as a schedule II substance under the CSA. 84 FR 48815. This rulemaking finalizes that NPRM.

Legal Authority

Under 21 U.S.C. 811(e), the Attorney General may place an immediate precursor into the same schedule as the controlled substance that the immediate precursor is used to make, if the substance meets the requirements of an immediate precursor under 21 U.S.C. 802(23).

Background

The DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl abroad. 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 in the United States for anesthesia and analgesia. However, due to its pharmacological effects, fentanyl can serve as a substitute for heroin, oxycodone, and other opioids in opioid dependent individuals. The 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.

The 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 related to 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 Norfentanyl 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 for creating a new organic molecule through a series of chemical reactions, which involve precursor 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).

[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 fentanyl category 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.

The DEA controlled NPP on April 23, 2007 as a list I chemical by interim rule (72 FR 20039), which was finalized on July 25, 2008. 73 FR 43355. By final rule published on June 29, 2010, ANPP was controlled as a schedule II immediate precursor to fentanyl, with an effective date of 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 increase of fentanyl on the illicit drug market. 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.

Recent law enforcement information indicates that illicit manufacturers of fentanyl also use other synthetic routes in response to regulations placed on NPP and ANPP. One of these other routes is the original published synthetic pathway to fentanyl, known as the Janssen method, previously thought to be beyond the skills of most clandestine laboratory operators. This synthetic route does not involve NPP or ANPP as precursors. This synthetic pathway involves the important precursors *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl). Benzylfentanyl is converted into norfentanyl in one chemical reaction. Norfentanyl is then subjected to one simple chemical reaction to complete the synthesis of fentanyl. The DEA is not aware of any legitimate uses of benzylfentanyl or norfentanyl other than in 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 increased in 2017 and 2018. As stated above, benzylfentanyl is a precursor chemical used to synthesize norfentanyl in the Janssen method. According to NFLIS,[5] there was one identification of benzylfentanyl in 2016; however, benzylfentanyl was identified in 195 reports in 2017 and 237 reports in 2018. This is believed to indicate a change in the synthetic route used by some clandestine chemists to manufacture fentanyl in efforts to evade chemical regulations on NPP and ANPP. The increase in law enforcement encounters coincides with the international control that placed NPP and ANPP in Table I of the 1988 Convention in 2017.

The DEA determined that norfentanyl is commercially available from both domestic and foreign chemical suppliers. The DEA has identified 30 domestic suppliers and 22 foreign suppliers of norfentanyl from Canada (3), China (7), Germany (2), Hong Kong (1), India (1), Japan (2), Switzerland (1), and the United Kingdom (5). Of the 30 domestic suppliers of norfentanyl, only one is a DEA registrant. As it appears that these other 29 suppliers are not registered to manufacture schedule II controlled substances, it is not likely these suppliers are manufacturing fentanyl. Norfentanyl is attractive to illicit manufacturers because of the lack of chemical regulations on this substance, it is readily available from chemical suppliers, and it can easily be converted to the schedule II controlled substance fentanyl, in a one-step chemical reaction.

Designation as an Immediate Precursor

Under 21 U.S.C. 811(e), the Attorney General may place an immediate precursor into the same schedule as the controlled substance that the immediate precursor is used to make. The substance must meet the requirements of an immediate precursor under 21 U.S.C. 802(23). The term ''immediate precursor'' is defined in 21 U.S.C. 802(23) meaning a substance being the principal compound used, or which is produced primarily for use in the manufacture of a controlled substance; which is an immediate chemical intermediary used or likely to be used in the manufacture of the controlled substance; and the control of which is necessary to prevent or limit the manufacture of such controlled substance.

The DEA finds that norfentanyl meets the three criteria for the definition of an immediate precursor under 21 U.S.C. 802(23). First, DEA finds that norfentanyl is produced primarily for use in the manufacture of the schedule II controlled substance fentanyl. As stated in the preceding section, under the Janssen method, norfentanyl is typically produced from the starting material benzylfentanyl and is then subjected to a simple one-step chemical reaction to obtain the schedule II controlled substance, fentanyl. The DEA is not aware of any legitimate use of benzylfentanyl other than in the synthesis of norfentanyl, and subsequently, fentanyl. The DEA has also not identified an industrial or other use for norfentanyl beyond the manufacture of fentanyl. DEA has not identified any other legitimate uses of norfentanyl and DEA did not receive comment to the contrary during the notice and comment period of the NPRM published on September 17, 2019. 84 FR 48815.

Second, DEA finds that norfentanyl is an immediate chemical intermediary used in the manufacture of the controlled substance fentanyl. As stated earlier, norfentanyl is produced as an intermediary in the fentanyl synthetic pathway. After it is synthesized, norfentanyl is subjected to a simple chemical reaction that converts it directly to fentanyl.

Third, DEA finds that controlling norfentanyl is necessary to prevent, curtail, and limit the unlawful manufacture of the controlled substance, fentanyl. The DEA believes this action is necessary to assist in preventing the possible theft of norfentanyl from legitimate firms. The DEA believes that clandestine manufacturers will attempt to procure unregulated chemicals in their efforts to synthesize fentanyl. As a schedule II substance, norfentanyl will be safeguarded to the same degree that pharmaceutical firms now safeguard the fentanyl that they produce. Since norfentanyl is an immediate chemical intermediary in the manufacture of fentanyl, the increased level of security is necessary to prevent diversion of norfentanyl from legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing norfentanyl and selling it (as an unregulated material) through the internet and other channels to individuals who may wish to acquire an unregulated precursor for the purpose of manufacturing fentanyl, a schedule II controlled substance.

The DEA believes that the control of norfentanyl is necessary to prevent its production and use in the illicit manufacture of fentanyl. Therefore, DEA is designating norfentanyl as an immediate precursor of fentanyl, a schedule II controlled substance, pursuant to 21 U.S.C. 802(23) and 21 U.S.C. 811(e).

Placement in Schedule II—Findings Required Under CSA Immediate Precursor Provisions

Pursuant to 21 U.S.C. 811(e), once norfentanyl is designated as an immediate precursor under 21 U.S.C. 802(23), it may be placed directly into schedule II (or a schedule with a higher numerical designation). The immediate precursor provision in 21 U.S.C. 811(e)

[5] NFLIS data was queried on March 26, 2019.

permits DEA to schedule an immediate precursor ''without regard to the findings required by'' section 811(a) or section 812(b) and ''without regard to the procedures'' prescribed by section 811(a) and (b). Accordingly, DEA need not address the ''factors determinative of control'' in section 811 or the findings required for placement in schedule II in section 812(b)(2). Based on the finding that norfentanyl is an ''immediate precursor'' for fentanyl, DEA is hereby placing norfentanyl directly into schedule II.

NPRM Comments

As part of the proposed rulemaking published on September 17, 2019 (84 FR 48815), DEA specifically solicited input from all potentially affected parties regarding: (1) The types of legitimate industries using norfentanyl; (2) the legitimate uses of norfentanyl; (3) the size of the domestic market for norfentanyl; (4) the number of manufacturers of norfentanyl; (5) the number of distributors of norfentanyl; (6) the level of import and export of norfentanyl; (7) the potential burden these proposed regulatory controls of norfentanyl may have on 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 norfentanyl by industry and others.

As part of the proposed rulemaking published on September 17, 2019 (84 FR 48815), DEA solicited information on any possible legitimate uses of norfentanyl unrelated to fentanyl production (including industrial uses) in order to assess the potential commercial impact of scheduling norfentanyl. The DEA searched information in the public domain for legitimate uses of norfentanyl and could not document legitimate commercial uses for norfentanyl other than as an intermediary chemical in the manufacture of fentanyl. DEA sought, however, to document any unpublicized use(s) and other proprietary use(s) of norfentanyl not in the public domain. Therefore, DEA solicited comment on the uses of norfentanyl in the legitimate marketplace. The DEA also solicited comment on the regulatory burden to legitimate commercial activities that would result from the placement of norfentanyl in schedule II of the CSA. The DEA did not receive comment on these topics.

The DEA invited all interested parties to provide any information on any legitimate uses of norfentanyl in industry, commerce, academia, research and development, or other applications. The DEA sought both quantitative and qualitative data; however, DEA did not receive comments on these topics.

The DEA received 15 comments in response to the NPRM. Thirteen of the 15 commenters were in support of controlling norfentanyl as a schedule II immediate precursor. The other two commenters did not specifically object to this rule. One of those two commenters stated that substance abuse is a public health issue and not a law enforcement issue. The other stated that this rule is not sufficient to disrupt the fentanyl market in the United States because illicit fentanyl is not produced in the United States. The commenter proposed access restriction and harm reduction strategies, including increased public awareness of drugs mixed with fentanyl and increased law enforcement at entry locations, as additional recommendations to reduce fentanyl misuse and abuse in the United States.

Of the 13 commenters in support of controlling norfentanyl as a schedule II immediate precursor, four commenters also included statements that the control of norfentanyl is not the only solution to address the opioid epidemic. These commenters stated that control of norfentanyl will not solve the issue of fentanyl being shipped into our country from foreign producers; that control of norfentanyl is not the only policy that should be addressed and implemented, and that alternate pathways to fentanyl should be monitored; and that control of norfentanyl will not end the opioid epidemic.

DEA response: The DEA appreciates the comments in support of controlling norfentanyl as a schedule II immediate precursor. The DEA is concerned with the abuse of illicitly manufactured fentanyl in the United States and abroad. While DEA remains aware that a comprehensive approach, to include community outreach and education, is required to combat the opioid epidemic, DEA believes that supply reduction strategies, which this rule attempts to address, are important aspects to reduce drug abuse in the United States. The control of norfentanyl as a schedule II immediate precursor is one aspect of the overall effort to combat the opioid epidemic. The DEA believes this rule will have a significant effect on reducing the supply of illicitly manufactured fentanyl.

With respect to the comments about illicit fentanyl being manufactured outside of the United States and shipped into the country from foreign producers, the designation of norfentanyl as a schedule II immediate precursor will subject this substance to the regulatory requirements of schedule II substances, including the import and export regulations. 21 CFR part 1312. The DEA believes that regulating the import and export of norfentanyl will reduce the quantity of norfentanyl destined to illicit fentanyl manufacturers, both domestically and internationally, by removing the United States as a transshipment point and as a source of diverted norfentanyl to foreign illicit fentanyl manufacturers.

The DEA is the leading agency on enforcement of drug control laws and remains committed to protecting the public by interrupting and reducing drug supply and availability in the United States. The DEA believes that the control of norfentanyl as an immediate precursor of the schedule II controlled substance fentanyl will have a significant impact on reducing the supply of illicitly manufactured fentanyl; however, DEA remains aware that supply reduction is not the only aspect of combatting the opioid epidemic. The DEA realizes that a comprehensive approach, to include community outreach and education, is required to combat the opioid epidemic. In response to the comment regarding access restriction and harm reduction strategies and the comment stating that substance abuse is a public health issue and not a law enforcement issue, DEA intends this scheduling action to reduce the supply of illicitly manufactured fentanyl, which is part of a multi-faceted strategy to combat the opioid epidemic. DEA continues to work with other federal agencies on holistic and comprehensive approaches to reduce drug abuse; however, such approaches are beyond the scope of this rule.

Requirements for Handling Norfentanyl

This rulemaking finalizes two actions. It (1) designates norfentanyl as an immediate precursor for the schedule II controlled substance, fentanyl, under the definition set forth in 21 U.S.C. 802(23); and (2) controls norfentanyl as a schedule II substance pursuant to the authority in 21 U.S.C. 811(e).

The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. The regulatory requirements will include the following:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports, or exports norfentanyl, engages in research with respect to norfentanyl, or proposes to engage in such activities will be required to submit an application and be accepted for schedule II registration in accordance with 21 CFR part 1301.

2. *Security.* Norfentanyl will be subject to schedule II security requirements. In order to prevent diversion, norfentanyl will be manufactured, distributed, and stored in accordance with the standards for physical security and the operating procedures set forth in 21 CFR 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b),(c), and (d) 1301.76, and 1301.77.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of norfentanyl that are distributed will be required to comply with the requirements of 21 CFR 1302.03–1302.07.

4. *Quotas.* Quotas for norfentanyl will be established pursuant to 21 CFR part 1303.

5. *Inventory.* Every registrant who possesses any quantity of norfentanyl will be required to keep an inventory of all stocks of the substance on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11.

6. *Records and Reports.* Every DEA registrant will be required to maintain records and submit reports with respect to norfentanyl pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes norfentanyl will be required to comply with the order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of norfentanyl will be required to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *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 controlled substance 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.

10. *Liability.* Any activity with norfentanyl in violation of or not authorized under the Controlled Substances Act or the Controlled Substances Import and Export Act will be unlawful and potentially subject to criminal penalties. 21 U.S.C. 841–863 and 959–964.

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 rulemaking 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 expected to be an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for the 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.

The DEA has not identified any industrial use for norfentanyl, other than its role as an intermediary chemical in the manufacture of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced from ANPP (schedule II immediate precursor for fentanyl), not norfentanyl. The quantities of ANPP permitted in the U.S., imported or manufactured pursuant to a quota, generally correspond with the quantities of legitimate pharmaceutical fentanyl produced in the United States. Additionally, DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, DEA cannot rule out the possibility that minimal quantities of norfentanyl are used for this purpose. If there are any quantities of norfentanyl used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant.

The DEA evaluated the costs and benefits of this action.

[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).

Costs

The DEA believes the market for norfentanyl for the legitimate manufacturing of pharmaceutical fentanyl is minimal. As stated above, the only use for norfentanyl of which DEA is aware is for the manufacturing of fentanyl. Any manufacturer, distributor, importer, or exporter of norfentanyl for the production of legitimate pharmaceutical fentanyl, if they exist at all, would incur costs. The primary costs associated with this rule include costs associated with complying with registration, physical security, labeling and packaging, quota, inventory, recordkeeping and reporting, and importation and exportation requirements. Other than the annual registration fees ($3,047 for manufacturers and $1,523 for distributors, importers, and exporters), due to the many unknowns and variability between entities, it is highly difficult to quantify the potential total cost burden of this regulation. However, any manufacturer that uses norfentanyl 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. Any lost sales or profit attributed to those manufacturers or suppliers that are not for legitimate pharmaceutical fentanyl are excluded from the analysis as they are, whether passively or actively, facilitating the manufacture of illicit fentanyl.

The DEA has identified 30 domestic suppliers of norfentanyl, 29 of which are not registered with DEA to handle schedule II controlled substances. It is difficult to estimate how much norfentanyl 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 fentanyl and ANPP, where the quantities of ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. Suppliers for the legitimate use of norfentanyl are expected to choose the least-cost option, and stop selling the minimal quantities, if any, of norfentanyl, rather than incur the costs of complying with the regulatory requirements. Because DEA believes the quantities of norfentanyl supplied for the legitimate manufacturing of pharmaceutical fentanyl is minimal, DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this rule is minimal.

This analysis excludes consideration of economic impact to those businesses that facilitate the manufacturing and distribution of norfentanyl for the manufacture of illicit fentanyl. The only use for norfentanyl of which DEA is currently aware is the manufacture of fentanyl. Although these suppliers are selling a currently unregulated substance, they wittingly or unwittingly facilitate the manufacturing of 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.

Benefits

Controlling norfentanyl is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substance, fentanyl. This action is also expected to assist preventing the possible theft or diversion of norfentanyl from any legitimate firms. As a schedule II substance, norfentanyl will be safeguarded to the same degree that pharmaceutical firms now safeguard the fentanyl that they produce. The DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing norfentanyl and selling it (as an unregulated material) through the internet and other channels, to individuals who may wish to acquire an unregulated precursor 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 norfentanyl. The DEA believes the market for norfentanyl for the legitimate manufacturing of pharmaceutical fentanyl is minimal. Therefore, any potential cost as a result of this regulation is minimal. Therefore, the estimated economic impact of this rule is less than $100 million in any given year.

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) (RFA), 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, the scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, subjects norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule II controlled substance. Norfentanyl is the immediate chemical intermediary in a synthesis process currently used by clandestine laboratory operators for 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.

The DEA has not identified any use for norfentanyl, other than its role as an intermediary chemical in the manufacture of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, DEA believes the vast majority, if not all, of legitimate pharmaceutical fentanyl is produced from ANPP (schedule II immediate precursor for fentanyl), not norfentanyl. The quantities of ANPP permitted in the U.S., imported or manufactured pursuant to a quota, generally correspond with the quantities of

legitimate pharmaceutical fentanyl produced in the United States. Additionally, DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, DEA cannot rule out the possibility that minimal quantities of norfentanyl are used for this purpose. If there are any quantities of norfentanyl used for the manufacturing of legitimate pharmaceutical fentanyl, the quantities are believed to be small and economically insignificant.

The DEA has identified 30 domestic suppliers of norfentanyl. Based on the Small Business Administration size standard for chemical distributors and Statistics of United States Business data, 94.5 percent or 28.4 (rounded to 28) are estimated to be small entities. It is difficult to know how much norfentanyl 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 fentanyl and ANPP, where the quantities of ANPP imported and manufactured generally correspond with the quantities of fentanyl produced, DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. Therefore, DEA estimates the cost of this rule on any affected small entity is minimal.

Because of these facts, 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 determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.,* that this action will 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 under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action does 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 1308

Administrative practice and procedure, drug traffic control, reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. Amend § 1308.12 by adding paragraph (g)(3)(ii) to read as follows.

§ 1308.12 Schedule II.

* * * * *

(g) * * *

(3) * * *

(ii) *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) 8366

* * * * *

Dated: March 5, 2020.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–07381 Filed 4–16–20; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2019–0083; FRL–10007–78–Region 7]

Air Plan Approval; Nebraska; Infrastructure SIP Requirements for the 2015 Ozone National Ambient Air Quality Standards (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve elements of a State Implementation Plan (SIP) submission from the State of Nebraska addressing the applicable requirements of the Clean Air Act (CAA) section 110 for the 2015 Ozone (O_3) National Ambient Air Quality Standards (NAAQS). Whenever the EPA promulgates a new or revised NAAQS, CAA section 110 requires that each State adopt and submit a SIP submission to establish that the State's SIP meets infrastructure requirements for the implementation, maintenance, and enforcement of each such new or revised NAAQS. These SIP submissions are commonly referred to as ''infrastructure'' SIPs. The infrastructure requirements are designed to ensure that the structural components of each State's air quality management program are adequate to meet the State's responsibilities under the CAA.

DATES: This final rule is effective on May 18, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2019–0083. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Lachala Kemp, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7214; email address *kemp.lachala@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents

I. Background

On May 9, 2019, the EPA proposed to approve Nebraska's infrastructure SIP submission for the 2015 O_3 NAAQS in the **Federal Register**. 84 FR 20318 (May 9, 2019). The EPA solicited comments on the proposed approval of the infrastructure SIP submission and