(ii) ''AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,'' in *Official Methods of Analysis of AOAC International,* Sec. 47.3.43 (2019), which is incorporated by reference. A copy of AOAC Official Method 990.28 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

■ 3. Remove and reserve Appendix A to Part 101.

PART 130—FOOD STANDARDS: GENERAL

■ 4. The authority citation for part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

■ 5. Amend § 130.9 by revising paragraph (a) to read as follows:

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable concentration is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million (ppm or mg/kg) or more of the sulfite in the finished food. The concentration of sulfite in the finished food will be determined using either:

(1) ''Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry,'' in *Journal of AOAC International,* Vol. 100, No. 6, pp. 1785–1794, which is incorporated by reference. A copy of *Journal of AOAC International,* Vol. 100, No. 6 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html;* or

(2) ''AOAC Official Method 990.28, Sulfites in Foods, Optimized Monier-Williams Method,'' in *Official Methods of Analysis of AOAC International,* Sec. 47.3.43 (2019), which is incorporated by reference. A copy of AOAC Official Method 990.28 is available from AOAC International, 2275 Research Blvd., Ste. 300, Rockville, MD 20850–3250, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

* * * * *

Dated: July 16, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: September 3, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–19862 Filed 9–16–19; 8:45 am]

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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: Notice of proposed rulemaking.

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

DATES: Comments must be submitted electronically or postmarked on or before November 18, 2019. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–496'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate the electronic submissions are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: 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: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

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

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

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

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. 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%) involved fentanyl.[2] Of the 63,632 drug overdose deaths in 2016, 18,335 (28.8%) 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%) 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% 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, the 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). 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. ANPP was controlled as a schedule II immediate precursor to fentanyl on August 30, 2010. 75 FR 37295. (June 29, 2010).

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, which is subject to a Notice of Proposed Rulemaking for control as a list I chemical published elsewhere in this issue of the **Federal Register**, is converted into norfentanyl in one chemical reaction. Norfentanyl is

[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.

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% 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'' as defined in 21 U.S.C. 802(23) means a substance:

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, 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, the 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. Although DEA has not identified any other legitimate uses of norfentanyl, this notice of proposed rulemaking provides the public an opportunity to provide information to the contrary, as described in the ''Solicitation for Information'' section below.

Second, the 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, the 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 effort 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. 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 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 production of fentanyl. Therefore, the DEA is proposing the designation of 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).

Proposed 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) permits the 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, the 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, the DEA proposes to place norfentanyl directly into schedule II.

Requirements for Handling Norfentanyl

The proposed scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, would subject 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. If norfentanyl is placed in schedule II, 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 would be required to submit an application and be accepted for

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

schedule II registration in accordance with 21 CFR part 1301.

2. *Security.* Norfentanyl would be subject to schedule II security requirements. In order to prevent diversion, norfentanyl would have to 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) and (c), 1301.76, and 1301.77.

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

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

5. *Inventory.* Every registrant who possesses any quantity of norfentanyl would 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 would 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 would 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 would 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. *Liability.* Any activity with norfentanyl in violation of or not authorized under the Controlled Substances Act or the Controlled Substances Import and Export Act would be unlawful and potentially subject to criminal penalties (21 U.S.C. 841–863 and 959–964).

Solicitation for Information

As part of this proposed rulemaking, the DEA is soliciting 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 has searched information in the public domain for legitimate uses of norfentanyl and has not documented legitimate commercial uses for norfentanyl other than as an intermediary chemical in the production of fentanyl. The DEA seeks, however, to document any unpublicized use(s) and other proprietary use(s) of norfentanyl not in the public domain. Therefore, the DEA is soliciting comment on the uses of norfentanyl in the legitimate marketplace. DEA is also soliciting comment on the regulatory burden to legitimate commercial activities that would result from the proposed placement of norfentanyl in schedule II of the CSA.

The DEA is soliciting 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. The DEA invites 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 seeks both quantitative and qualitative data.

Handling of Confidential or Proprietary Information

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

Regulatory Analyses

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

This proposed rule 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. The DEA has determined that this proposed 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 proposed rule is not expected to be an E.O. 13771 regulatory action because this proposed rule is not significant under E.O. 12866.

The scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, would subject norfentanyl to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution,

[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).

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 production of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, the 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 U.S. Additionally, the DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, the 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 proposed action.

Costs

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 the 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 if this proposed rule were finalized. The primary costs associated with this proposed 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 proposed regulation. However, any manufacturer that uses norfentanyl for legitimate pharmaceutical fentanyl production would already be registered with the 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 the 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, the DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. If this proposed rule is finalized, 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 the DEA believes the quantities of norfentanyl supplied for the legitimate manufacturing of pharmaceutical fentanyl is minimal, the DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this proposed rule is minimal. The DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of economic impact to those businesses that facilitate the manufacturing and distribution of norfentanyl for the production of manufacturing illicit fentanyl. The only use for norfentanyl of which the DEA is currently aware is the production 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, the 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 would 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, the DEA conducted a qualitative analysis of costs and benefits. The DEA believes this action, if finalized, 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 proposed rule is less than $100 million in any given year.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. This proposed rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and

Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. As discussed above, the proposed scheduling of norfentanyl as an immediate precursor of the schedule II controlled substance, fentanyl, would subject 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 production of fentanyl. Based on the review of import and quota information for ANPP and fentanyl, the 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 U.S. Additionally, the DEA is not aware of norfentanyl being used for the manufacturing of legitimate pharmaceutical fentanyl; however, the 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 Small Business Administration size standard for chemical distributors and Statistics of U.S. Business data, 94.5% 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, the DEA believes any quantity of sales from these distributors for the legitimate pharmaceutical fentanyl manufacturing is minimal. Therefore, the DEA estimates the cost of this rule on any affected small entity is minimal. The DEA welcomes any public comment regarding this estimate.

Because of these facts, this proposed rule will not, if promulgated, 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, the DEA 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 proposed action does not impose a new collection of information under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This proposed 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 1308

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

For the reasons set out above, the DEA proposes to amend 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 a new paragraph (g)(3)(ii) and adding and reserving paragraph (g)(3)(iii) to read as follows.

§ 1308.12 Schedule II.

* * * * *

(g) * * *

(3) * * *

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

(iii) [Reserved]

* * * * *

Dated: September 6, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–19786 Filed 9–16–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 92, 93, 574, 960, 966, 982

[Docket No FR–6057–P–01]

RIN 2577–AD03

Housing Opportunity Through Modernization Act of 2016: Implementation of Sections 102, 103, and 104

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, Office of the Assistant Secretary for Housing-Federal Housing Commissioner, and Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Proposed rule.

SUMMARY: The Housing Opportunity Through Modernization Act of 2016 (HOTMA) was enacted on July 29, 2016. This proposed rule would revise HUD regulations to put sections 102, 103, and 104 of HOTMA into effect. These sections make sweeping changes to the United States Housing Act of 1937, particularly those affecting income calculation and reviews. Section 102 changes requirements pertaining to income reviews for public housing and HUD's Section 8 programs. Section 103 modifies the continued occupancy standards of public housing residents whose income has grown above the threshold for initial eligibility. Section 104 sets maximum limits on the assets that families residing in public housing and Section 8 assisted housing may have. Additionally, section 104 provides that HUD must direct public housing agencies to require that all applicants for and recipients of assistance through HUD's public housing or Section 8