PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, Airspace Designations and Reporting Points, dated August 15, 2007, and effective September 15, 2007, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASW NM D Albuquerque, NM [New]

Double Eagle II Airport, NM
(Lat. 35°08′42″ N., long. 106°42′40″ W.)
Dudle NDB (LOM)
(Lat. 35°13′02″ W., long. 106°42′46″ W.)

That airspace extending upward from the surface to and including 7,500 feet MSL within a 4.3 mile radius of Double Eagle II Airport, and within 1 mile each side of the Double Eagle Runway 22 ILS localizer course, extending northeast from the 4.3 mile radius to the DUDLE NDB (LOM) excluding that airspace within the Albuquerque International Airport Class C airspace area. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Fort Worth, TX on March 31, 2008.

Walter Tweedy,

Acting Manager, System Support Group, ATO Central Service Center.

[FR Doc. E8–7267 Filed 4–8–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–305P]

RIN 1117–AB16

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

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to designate the precursor chemical, 4-anilino-N-phenethyl-4-piperidine (ANPP) as an immediate precursor for the schedule II controlled substance, fentanyl, under the definition set forth in 21 U.S.C. § 802(23). Furthermore, DEA is proposing to control ANPP as a schedule II substance under the Controlled Substances Act (CSA), pursuant to the authority in 21 U.S.C. 811(e), which states that an immediate precursor may be placed in the same schedule as the controlled substance it produces, without the need of addressing the ''factors determinative of control'' in 21 U.S.C. § 811 or the findings required in 21 U.S.C. 812(b).

ANPP is the immediate chemical intermediary in the 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 hundreds of fentanyl-related overdoses in the United States in recent months. DEA believes that the control of ANPP as a schedule II controlled substance is necessary to prevent its diversion as an immediate chemical intermediary for the illicit production of fentanyl.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before June 9, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–305'' on all written and electronic correspondence. Written comments via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent directly to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket 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 posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 at (202) 307–7183.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) is extremely concerned with the recent increase in the illicit manufacture and distribution of fentanyl, which has

resulted in hundreds of fentanyl-related overdoses and fentanyl-related deaths in several areas of the country. DEA is proposing to designate the precursor chemical, 4-anilino-N-phenethyl-4-piperidine (ANPP) as an immediate precursor for the schedule II controlled substance fentanyl under the definition set forth in 21 U.S.C. 802(23).

Under the immediate precursor provision in 21 U.S.C. 811(e), DEA may 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). Because of the authority in section 811(e), 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), and accordingly, DEA is not seeking comment on those factors and/or findings in this NPRM.

This rulemaking proposes two actions. It (1) proposes the designation of the precursor chemical ANPP 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) proposes control of ANPP as a schedule II substance pursuant to the authority in 21 U.S.C. 811(e). DEA is soliciting comment on these two proposed actions, as well as on any possible legitimate uses of ANPP that are unrelated to fentanyl (including industrial uses) in order to assess the potential commercial impact of scheduling ANPP.

Background

Fentanyl is a schedule II controlled substance. Fentanyl and analogues of fentanyl are the most potent opioids available for human and veterinary use. Fentanyl produces opioid effects that are indistinguishable from morphine or heroin, but fentanyl has a greater potency and a shorter duration of action. Fentanyl is approximately 50 to 100 times more potent than morphine and 30 to 50 times more potent than heroin, depending on the physiological or behavioral measure, the route of administration, and other factors.

The legitimate medical use of fentanyl is for anesthesia and analgesia, but fentanyl's euphoric effects are highly sought after by narcotic addicts. Fentanyl can serve as a direct pharmacological substitute for heroin in opioid-dependent individuals. Fentanyl is a very dangerous substitute for heroin, however, because the amount that produces a euphoric effect also induces respiratory depression. Furthermore, due to fentanyl's greater potency, illicit drug dealers have trouble adjusting (''cutting'') pure fentanyl into non-lethal dosage concentrations. Heroin users similarly have difficulty determining how much to take to get their ''high'' and sometimes mistakenly take a lethal quantity of the fentanyl. Unfortunately, only a slight excess of fentanyl can be, and is often, lethal, because the resulting level of respiratory depression is sufficient to cause the user to stop breathing.

Illicit Fentanyl-Related Deaths

In 2005 and 2006, DEA saw a sharp increase in the seizures of illicit fentanyl. The distribution of illicit fentanyl or illicit fentanyl combined with heroin or with cocaine (i.e., a ''speedball'') resulted in an outbreak of hundreds of confirmed and suspected fentanyl-related overdose deaths in the United States since April 2005, according to the Centers for Disease Control and Prevention (CDC) and medical examiners representing numerous cities and counties across the United States. DEA terms fentanyl-related deaths ''suspected'' until confirmed through the completion of an autopsy, a positive toxicological testing result for fentanyl in the blood, and the reporting of the death to the DEA.

To address this emergency health situation, DEA published an Interim Final Rule ''Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I chemical'' (72 FR 20039, April 23, 2007) to control N-phenethyl-4-piperidone (NPP), the chemical precursor to ANPP, as a List I chemical. As DEA discussed extensively in that Interim Final Rule, at least 972 confirmed fentanyl-related deaths, and 162 suspected fentanyl-related deaths, mostly in Delaware, Illinois, Maryland, Michigan, Missouri, New Jersey, and Pennsylvania were initially reported to the DEA. The number of fentanyl-related deaths significantly decreased after October 2006 and continued at lower levels following control of the precursor NPP in 2007.

From the information and data collected, there is a strong indication that the fentanyl in these confirmed and suspected fentanyl-related deaths is the result of illicitly manufactured fentanyl, rather than from fentanyl diverted from legal pharmaceutical manufacturers. Forensic testing of seized fentanyl drug exhibits can identify manufacture procedure markers such as benzylfentanyl and ANPP. The forensic data suggests that most of these fentanyl-related deaths are from fentanyl illicitly manufactured by the procedure called the Siegfried method, discussed in DEA's Interim Final Rule, which uses NPP/ANPP.

Synthesis of Fentanyl

DEA has determined from the forensic testing of seized illicit fentanyl that two primary synthesis routes (*i.e.*, the Janssen synthesis route and the Siegfried method) are being used to produce fentanyl clandestinely. In 1965, Janssen Pharmaceutical patented the original synthesis procedure for fentanyl. The Janssen synthesis route is difficult to perform and is beyond the rudimentary skills of most clandestine laboratory operators. Only individuals who have acquired advanced chemistry knowledge and skills have successfully used this synthesis route. Forensic laboratories can determine whether fentanyl was manufactured illicitly by the Janssen route by detecting the impurity benzylfentanyl in the tested fentanyl drug exhibit.

In the early 1980s, an alternate route for fentanyl synthesis was published in the scientific literature; it uses N-phenethyl-4-piperidone (NPP) as the starting material. The NPP synthesis route is described on the Internet and is referred to as the Siegfried method. The chemical intermediary ANPP is produced during the synthesis and is the immediate precursor used in the illicit manufacture of fentanyl in the last stage of the Siegfried method. The Chemical Abstracts Service Registry Number[1] (CASRN) for ANPP is 21409–26–7. The detection of the impurity 4-anilino-N-phenethyl-4-piperidine (ANPP) without the presence of benzylfentanyl in the fentanyl drug exhibit suggests that the fentanyl was manufactured by the Siegfried method (or a modified version) that produces the precursor ANPP and then converts ANPP directly to fentanyl. (A small amount of ANPP is not consumed in the last reaction in the synthesis, and thus a trace amount of ANPP remains in the fentanyl.)

The increase in street-level fentanyl may be the result of the relative ease with which fentanyl can be produced via the Siegfried method and the widespread distribution of the Siegfried method on the Internet. Preliminary data indicate that the majority of the deaths in the current fentanyl outbreak have resulted from the distribution of

[1] The Chemical Abstracts Service Registry Number (CASRN) is created by the Chemical Abstracts Service (CAS) Division of the American Chemical Society and is part of an automated information system housing data and information on specific, definable chemical substances. The CASRN provides consistent and unambiguous identification of chemicals and facilitates sharing of chemical information.

illicit fentanyl made by the Siegfried method and marked by traces of ANPP rather than benzylfentanyl.

Role of ANPP in Synthesis of Fentanyl

Since 2000, four of the five domestic fentanyl clandestine laboratories seized by law enforcement agents have used the Siegfried method or a modified version of the Siegfried method in manufacturing fentanyl. The amount of illicit fentanyl and precursor chemicals found at these four laboratories could have generated a total of 5,800 grams of illicit fentanyl. Since fentanyl is potent in sub-milligram quantities, the subsequent ''cutting'' of 5,800 grams of illicit fentanyl would be sufficient to make about 46 million fentanyl doses.

The precursor chemical NPP is the starting material utilized in the Siegfried method of synthesizing fentanyl, both in industry and in illicit drug laboratories. Under a separate rulemaking published April 23, 2007 (72 FR 20039), DEA has controlled the precursor NPP as a List I chemical under the regulatory control provisions of the CSA (21 CFR part 1300).

During the production process, the starting material, NPP, is subjected to a series of chemical reactions in order to produce the intermediary chemical ANPP. The ANPP is then subjected to a simple chemical reaction resulting in the synthesis of fentanyl. DEA has not identified any industrial uses for ANPP and believes that ANPP is only produced as a chemical intermediary in the production of fentanyl, either in the legitimate production of pharmaceutical fentanyl or the illicit production of fentanyl in clandestine laboratories. ANPP is, therefore, an immediate chemical intermediary in the synthesis of fentanyl and is produced primarily for this purpose.

DEA is proposing to control ANPP as a schedule II controlled substance in an effort to prevent its use in production of illicit fentanyl. DEA believes control is necessary to prevent unscrupulous chemists from synthesizing and distributing ANPP (as an unregulated material), and selling it through the Internet and other channels to individuals who may wish to acquire an unregulated precursor for fentanyl synthesis. DEA believes this action is also advisable in order to deter the theft of ANPP from legitimate pharmaceutical firms where it is generated in the course of fentanyl production. It has been determined by DEA's Office of Forensic Sciences that ANPP can also be produced through synthetic pathways that do not require NPP as the starting material. Therefore, DEA believes that controlling ANPP directly is necessary to prevent the illicit production of fentanyl.

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.

DEA finds that ANPP meets the three criteria for the definition of an immediate precursor under 21 U.S.C 802(23). First, DEA finds that ANPP is produced primarily for use in the manufacture of the schedule II controlled substance fentanyl. As stated in the preceding section, under the Siegfried method, ANPP is typically produced from the starting material NPP and is then subjected to a simple one-step chemical reaction to obtain the schedule II controlled substance fentanyl. DEA has not identified any industrial or other uses for ANPP and believes that it is produced primarily during the synthesis of fentanyl.

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

Third, DEA finds that controlling ANPP is necessary to prevent, curtail, and limit the unlawful manufacture of the controlled substance fentanyl. As noted above, DEA believes this action is necessary to assist in preventing the possible theft of ANPP from legitimate pharmaceutical firms where it is a chemical intermediary generated for fentanyl production. As a schedule II substance, ANPP will be safeguarded to the same degree that pharmaceutical firms now safeguard the fentanyl that they produce. DEA believes this increased level of security is necessary to prevent diversion of ANPP.

As noted previously, ANPP can also be produced through synthetic pathways that do not require NPP as the precursor material. Accordingly, DEA believes control is necessary to prevent unscrupulous chemists from synthesizing ANPP and selling it (as an unregulated material) through the Internet and other channels to individuals who may wish to acquire an unregulated precursor for fentanyl synthesis, in order to circumvent the regulation of NPP as a List I chemical.

DEA believes that the control of ANPP is necessary to prevent its production and use in the illicit production of fentanyl. Therefore, DEA is proposing the designation of ANPP as an immediate precursor of fentanyl 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

Under the authority in 21 U.S.C. 811(e), once ANPP 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 DEA to schedule an immediate precursor ''without regard to the findings required by'' § 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).[2]

Furthermore, if ANPP is designated as an ''immediate precursor'' for the schedule II controlled substance fentanyl, section 811(e) specifies that DEA does not need to make the findings

[2] Under administrative scheduling of a substance pursuant to 21 U.S.C. 811(c), DEA must consider the ''factors determinative of control.'' The DEA must consider the following factors with respect to each drug or other substance proposed to be controlled in a schedule:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the drug or other substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled.

21 U.S.C. 811(e) specifies that none of these factors must be considered, however, in the control of an ''immediate precursor.''

required under section 812(b)(2) for schedule II controlled substances.[3]

Based on the finding that ANPP is an ''immediate precursor'' for fentanyl, DEA proposes to place ANPP directly into schedule II. Therefore, DEA is not seeking comments regarding these factors and findings.

Requirements for Handling Schedule II Substances

The proposed scheduling of ANPP as an immediate precursor would subject ANPP 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. Therefore, DEA is soliciting comment from manufacturers, distributors, importers, exporters, and researchers on the regulatory burden to legitimate commercial activities that would result from the proposed placement of ANPP in schedule II of the CSA.

To date DEA has not identified any legitimate industrial use for ANPP, other than its role as an intermediary chemical in the production of fentanyl by the pharmaceutical industry. If ANPP is used only to manufacture fentanyl, the potential regulation of ANPP as an immediate precursor will not represent a new, major regulatory burden because fentanyl manufacturers have already implemented the CSA requirements for schedule II substances. For example, since fentanyl is a schedule II controlled substance, these firms will already be schedule II registrants and will already have adequate schedule II security. As a result of this rulemaking, these firms will need to begin storing ANPP under the same security controls already used for the final product fentanyl. The impact upon legitimate industry of controlling ANPP as a schedule II substance should be minimal. If ANPP is placed in schedule II, the regulatory requirements will include the following:

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

Security. ANPP would be subject to schedule II security requirements. In order to prevent diversion, ANPP 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.

This rule does not propose any new security requirements for schedule II controlled substances. The following existing security requirements are provided for informational purposes only.

Existing DEA physical security regulations require that, for schedule I and II controlled substances, raw material, bulk materials awaiting further processing, and finished products be stored in either a safe or steel cabinet (if the quantity is small) or in a vault (21 CFR 1301.72). DEA regulations set forth specific requirements regarding these structures. Controlled substances must be stored in these facilities during the manufacturing process except where a continuous manufacturing process should not be interrupted (21 CFR 1301.73). Secure storage areas are required to have an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or to a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or other protection as approved by DEA (21 CFR 1301.72(a)(1)(iii), 1301.72(a)(3)(iv)). The controlled substances storage areas are required to be accessible only to an absolute minimum number of specifically authorized employees (21 CFR 1301.72(d)). When it is necessary for other personnel or guests to be present in, or pass through, such secure areas, the registrant shall provide for adequate observation of the area by an employee (21 CFR 1301.72(d), 1301.73(c)).

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

Quotas. Quotas for ANPP would be established pursuant to 21 CFR part 1303.

Inventory. Every registrant who possesses any quantity of ANPP 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.

Records. All registrants would be required to keep records pursuant to 21 CFR 1304.03, 1304.04, and 1304.21–1304.23.

Reports. All registrants would be required to submit reports in accordance with 21 CFR 1304.33.

Orders. All registrants involved in the distribution of ANPP would be required to comply with the order requirements of 21 CFR part 1305.

Importation and Exportation. All registrants involved in the importation and exportation of ANPP would be required to comply with 21 CFR part 1312.

Prescriptions. All prescriptions for ANPP or prescriptions for products containing ANPP would be required to be issued pursuant to 21 CFR 1306.03–1306.06 and 21 CFR 1306.11–1306.15.

Criminal Liability. Any activity with ANPP 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 of Information

As part of this rulemaking, DEA is soliciting information on any possible legitimate uses of ANPP unrelated to fentanyl (including industrial uses) in order to assess the potential commercial impact of scheduling ANPP. DEA has searched information in the public domain for legitimate uses of ANPP and has not documented any legitimate commercial uses for ANPP other than as an intermediary chemical in the production of fentanyl. DEA seeks, however, to document any unpublicized use(s) and other proprietary use(s) of ANPP that are not in the public domain. Therefore, DEA is soliciting comment on the uses of ANPP in the legitimate marketplace.

DEA is soliciting input from all potentially affected parties regarding: (1) The types of legitimate industries using ANPP; (2) the legitimate uses of ANPP; (3) the size of the domestic market for ANPP; (4) the number of manufacturers of ANPP; (5) the number of distributors of ANPP; (6) the level of import and export of ANPP; (7) the potential burden these proposed regulatory controls of ANPP 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 ANPP by industry and others. DEA invites all interested parties to provide any information on any legitimate uses of ANPP in industry, commerce, academia, research and

[3] The findings for schedule II include (A) the drug or other substance has a high potential for abuse; (B) the drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and (C) abuse of the drug or other substance may lead to severe psychological or physical dependence.

development, or other applications. DEA seeks both quantitative and qualitative data.

Handling of Confidential or Proprietary Information

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

Regulatory Certifications

Regulatory Flexibility and Small Business Concerns

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to determine whether a proposed rule will have a significant economic impact on a substantial number of small entities. If an agency finds that there is a significant economic impact on a substantial number of small entities, the agency must consider whether alternative approaches could mitigate the impact on small entities. The size criteria for small entities are defined by the Small Business Administration (SBA) in 13 CFR 121.201.

DEA has not identified any legitimate industrial use for ANPP, other than its role as an intermediary chemical in the production of fentanyl by the pharmaceutical industry. DEA has not identified any firms that import, export, or distribute ANPP. If ANPP is used only to manufacture fentanyl, the potential regulation of ANPP as an immediate precursor will not represent a new, major regulatory burden, because fentanyl manufacturers have already implemented the CSA requirements for the handling of schedule II substances. Consequently, DEA believes the proposed rule will not have a significant economic impact on a substantial number of small entities. However, DEA is nonetheless seeking comment on whether there are uses for ANPP not known to DEA that could be impaired by this proposed rule and result in a significant economic impact on a substantial number of small entities.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

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, 21 CFR part 1308 is proposed to be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.12 is proposed to be amended by adding a new paragraph (g)(3) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(g) * * *

(3) Immediate precursor to fentanyl:

(i) 4-anilino-N-phenethyl-4-piperidine (ANPP) 8333

(ii) [Reserved]

Dated: March 14, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–7391 Filed 4–8–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 26, 27

RIN 1076–AE88

Job Placement and Training

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: This rule would consolidate requirements governing the Employment Assistance Program and the Adult Vocational Training Program. These programs assist Indian people to obtain job skills and to obtain and retain permanent employment. Combining these regulations will be consistent with changes to the Department's budget, which has combined these two regulations into one line item.

DATES: Submit comments on or before *July 8, 2008.*

ADDRESSES: Comments should be sent to Robert W. Middleton, PhD, Director, Office of Indian Energy and Economic Development, either by facsimile at (202) 208–4564, or by mail to 1951 Constitution Avenue, NW., Mailstop 20–SIB, Washington, DC 20245 or via the Federal rule making portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments on the information collection burden, including comments on or requests for copies of the [name of application form], are separate from those on the substance of the rule.

Send comments on the information collection burden to: Desk Officer for the Department of the Interior Office of Management & Budget, e-mail: *oira_docket@omb.eop.gov*, or (202) 395–6566 (fax). Please also send a copy of your comments to BIA at one of the addresses shown above.

FOR FURTHER INFORMATION CONTACT: You may request further information or obtain copies of the proposed information collection request from Lynn Forcia, Chief, Division of Workforce Development, telephone (202) 219–5270 or Jody Garrison, Manpower Development Specialist, at (202) 208–2685.

SUPPLEMENTARY INFORMATION: