signed August 27, 2009, and effective September 15, 2009 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM WA, ES Kelso, WA [Modified]

Southwest Washington Regional Airport, WA
(Lat. 46°07′05″ N., long. 122°53′54″ W.)

* * * * *

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Southwest Washington Regional Airport, and 2.4 miles each side of the 290° bearing of the airport extending 9.1 miles west, and 4.3 miles each side of the 337° bearing of the airport extending 22.2 miles northwest, and 5.8 miles west and 3 miles east of the 012° bearing of the airport extending 18.2 miles north of the airport.

Issued in Seattle, Washington, on June 14, 2010.

Kevin Nolan,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2010–15436 Filed 6–28–10; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. FDA–2010–N–0010]

Change of Address; Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to update the address for applicants to submit abbreviated new drug applications (ANDAs) and ANDA amendments, supplements, and resubmissions. FDA is also updating the address for ANDA applicants to submit investigational new drug applications (INDs) for in vivo bioavailability and bioequivalence studies in humans that are intended to support ANDAs. This action is being taken to ensure accuracy and clarity in the agency's regulations.

DATES: This rule is effective August 1, 2010.

FOR FURTHER INFORMATION CONTACT: Martin Shimer, Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., MPN II, Rockville, MD 20855, 240–276–8675.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 314.440(a)(2) to update the address for applicants to submit ANDAs and ANDA amendments, supplements, and resubmissions. FDA is also amending 21 CFR 312.140(a)(1) to update the address for ANDA applicants to submit INDs for in vivo bioavailability and bioequivalence studies that are intended to support ANDAs. The new address for all these submissions is Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North VII, 7620 Standish Pl., Rockville, MD 20855. This action is being taken to ensure accuracy and clarity in the agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update an address for the submission of ANDAs; ANDA amendments, supplements, and resubmissions; and INDs related to ANDAs.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 314 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

§ 312.140 [Amended]

■ 2. Section 312.140 is amended in paragraph (a)(1) by removing "II, 7500" and adding in its place "VII, 7620".

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 3. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.440 [Amended]

■ 4. Section 314.440 is amended in the first sentence of paragraph (a)(2) by removing "II, 7500 Standish Place., rm. 150" and adding in its place "VII, 7620 Standish Pl.".

Dated: June 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15711 Filed 6–28–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–305F]

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: Final Rule.

SUMMARY: The Drug Enforcement Administration (DEA) is designating 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 finalizing the control of 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 regard to the procedures required by 21 U.S.C. 811(a) and (b) and without regard to the findings required by 21 U.S.C. 811(a) and 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. In 2005 and 2006, the distribution of illicitly manufactured fentanyl caused an unprecedented outbreak of hundreds of fentanyl-related

overdoses in the United States. 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: This rulemaking becomes effective August 30, 2010.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152 at (202) 307–7183.

SUPPLEMENTARY INFORMATION: The 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. Therefore, on April 9, 2008, DEA published a Notice of Proposed Rulemaking (NPRM) [73 FR 19175] 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). This rulemaking finalizes that NPRM.

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).

This rulemaking finalizes two actions. It (1) designates 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) controls ANPP as a schedule II substance pursuant to the authority in 21 U.S.C. 811(e).

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 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), followed by a Final Rule (73 FR 43355, July 25, 2008), 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

[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.

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 2005–2006 fentanyl outbreak have resulted from the distribution of 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 first published as an interim rule on April 23, 2007 (72 FR 20039), followed by a final rule on July 25, 2008 (73 FR 43355), 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 controlling 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 designating ANPP as an immediate precursor of fentanyl 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

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" 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(c) [2] or the

[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;

Continued

findings required for placement in schedule II in section 812(b)(2).[3]

Based on the finding that ANPP is an "immediate precursor" for fentanyl, DEA is hereby placing ANPP directly into schedule II.

NPRM Comments

As part of this NPRM, DEA solicited comments and requested information on any possible legitimate uses of ANPP unrelated to fentanyl (including industrial uses) to assess the potential commercial impact of scheduling ANPP. DEA solicited 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 invited all interested parties to provide any information on any legitimate uses of ANPP in industry, commerce, academia, research and development, or other applications.

In response to the NPRM, DEA received only one comment. The commenter expressed concerns that the Aggregate Production Quotas for ANPP would need to take into account production losses that are inherent in the manufacture of fentanyl. Additionally, the commenter expressed concerns that the effective date of the rulemaking may adversely impact the timetable for production of fentanyl, since manufacturers would be required to obtain ANPP registrations and manufacturing quotas prior to being able to produce fentanyl.

In response to this comment, DEA recognizes that the ANPP Aggregate Production Quota must be established at a level that allows adequate production losses. Additionally, DEA is aware of the concerns of fentanyl manufacturers and will use its best efforts to minimize the impact of the new ANPP regulations on the legitimate production of fentanyl for medical use. Any person who manufactures, distributes, imports, exports, engages in research or conducts instructional activities with ANPP, or who desires to manufacture, distribute, import, export, engage in instructional activities or conduct research with ANPP, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Current bulk manufacturers, importers, and exporters of ANPP must submit an application for registration or an application to amend an existing registration to include ANPP on or before August 30, 2010 and may continue their activities until DEA has approved or denied that application.

Requirements for Handling Schedule II Substances

This rulemaking finalizes two actions. It (1) designates 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) controls ANPP as a schedule II substance pursuant to the authority in 21 U.S.C. 811(e).

The scheduling of ANPP as an immediate precursor will 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.

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 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. The regulatory requirements will include the following:

Registration. Any person who manufactures, distributes, imports, exports, engages in research or conducts instructional activities with ANPP, or who desires to manufacture, distribute, import, export, engage in instructional activities or conduct research with ANPP, must be registered to conduct such activities in accordance with 21 CFR part 1301. Current bulk manufacturers, importers and exporters of ANPP must submit an application for registration or an application to amend an existing registration to include ANPP on or before August 30, 2010 and may continue their activities until DEA has approved or denied that application.

Security. ANPP will be subject to schedule II security requirements. To prevent diversion, ANPP will 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 establish 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

(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."

[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.

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 will be required to comply with the requirements of 21 CFR 1302.03–1302.07.

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

Inventory. Every registrant who possesses any quantity of ANPP 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.

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

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

Orders. All registrants involved in the distribution of ANPP will 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 will be required to comply with 21 CFR part 1312.

Prescriptions. All prescriptions for ANPP or prescriptions for products containing ANPP will 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 will be unlawful and potentially subject to criminal penalties (21 U.S.C. 841–863 and 959–964).

Regulatory Certifications

Regulatory Flexibility and Small Business Concerns

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to determine whether a 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 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 this rule will not have a significant economic impact on a substantial number of small entities. DEA did not receive any comments suggesting that this rule will result in a significant economic impact on any small entities.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget.

DEA is regulating ANPP as a schedule II substance. Any person manufacturing, distributing, dispensing, conducting research with, importing, or exporting ANPP will have to register each location where ANPP is handled, maintain records of transactions involving ANPP, and take steps to ensure that inventories are secure (e.g., stored in sealed containers in areas where access can be controlled or monitored). DEA has not identified any domestic chemical companies that distribute ANPP, other than the production as an intermediate during the manufacture of fentanyl. Such manufacturers are already registered with DEA for the schedule II drug fentanyl.

Executive Order 12988

This regulation meets the applicable standards set forth in §§ 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 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 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: June 19, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–15520 Filed 6–28–10; 8:45 am]

BILLING CODE 4410–09–P