

**DATES:** *Effective Date:* This amendment will become effective on October 1, 2008.

**ADDRESSES:** Requests for copies of this document should be sent to: Public Reference Branch, Federal Trade Commission, Room 130, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Copies of this document are also available on the Internet at the Commission's Web site: <http://www.ftc.gov>.

**FOR FURTHER INFORMATION CONTACT:** Kelly A. Horne, (202) 326-3031, Division of Planning & Information, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** To comply with the Do-Not-Call Registry Fee Extension Act of 2007 (Pub. L. 110-188, 122 Stat. 635) ("Act"), the Commission is revising the Final Amended Fee Rule in the following manner: The revised rule decreases the annual fee for access to the Registry for each area code of data to \$54 per area code, or \$27 per area code of data during the second six months of an entity's annual subscription period. The maximum amount that would be charged to any single entity for accessing area codes of data is decreased to \$14,850. The revised rule retains the provisions regarding free access to the first five area codes of data by all entities, as well as free access by "exempt" organizations. As required by the Act, it expands the definition of "exempt" organizations to include any person permitted to access, but not required to access, the do-not-call registry, not only under the TSR, the Federal Communication Commission's do-not-call rules found at 47 CFR 64.1200, or any other Federal law, but also under *any other Federal regulation*.

Additionally, in accordance with the Act, beginning after fiscal year 2009, the dollar amounts charged shall be increased by an amount equal to the amounts specified in the Final Amended Fee Rule, whichever fee is applicable, multiplied by the percentage (if any) by which the average of the monthly consumer price index (for all urban consumers published by the Department of Labor) ("CPI") for the most recently ended 12-month period ending on June 30 exceeds the CPI for the 12-month period ending June 30, 2008. Any increase shall be rounded to the nearest dollar. There shall be no increase in the dollar amounts if the change in the CPI is less than 1 percent. The adjustments to the applicable fees, if any, shall be published in the **Federal**

**Register** no later than September 1 of each year.

**Administrative Procedure Act; Regulatory Flexibility Act; Paperwork Reduction Act**

The revisions to the Fee Rule are technical in nature and merely incorporate statutory changes to the TSR. These statutory changes have been adopted without change or interpretation at this time, making public comment unnecessary. Therefore, the Commission has determined that the notice and comment requirements of the Administrative Procedure Act do not apply. *See* 5 U.S.C. 553(b). For this reason, the requirements of the Regulatory Flexibility Act also do not apply. *See* 5 U.S.C. 603, 604.

Pursuant to the Paperwork Reduction Act, 44 U.S.C. 3501-3521, the Office of Management and Budget ("OMB") approved the information collection requirements in the Amended TSR and assigned the following existing OMB Control Number: 3084-0097. The amendments outlined in this Final Rule pertain only to the fee provision (sec. 310.8) of the Amended TSR and will not establish or alter any recordkeeping, reporting, or third-party disclosure requirements elsewhere in the Amended TSR.

■ Accordingly, the Federal Trade Commission amends part 310 of title 16 of the Code of Federal Regulations as follows:

**PART 310—TELEMARKETING SALES RULE**

■ 1. The authority citation for part 310 continues to read as follows:

**Authority:** 15 U.S.C. 6101-6108; 15 U.S.C. 6151-6155.

■ 2. Revise §§ 310.8(c) and (d) to read as follows:

**§ 310.8 Fee for access to the National Do Not Call Registry.**

\* \* \* \* \*

(c) The annual fee, which must be paid by any person prior to obtaining access to the National Do Not Call Registry, is \$54 for each area code of data accessed, up to a maximum of \$14,850; *provided*, however, that there shall be no charge to any person for accessing the first five area codes of data, and *provided further*, that there shall be no charge to any person engaging in or causing others to engage in outbound telephone calls to consumers and who is accessing area codes of data in the National Do Not Call Registry if the person is permitted to access, but is not required to access,

the National Do Not Call Registry under this Rule, 47 CFR 64.1200, or any other Federal regulation or law. Any person accessing the National Do Not Call Registry may not participate in any arrangement to share the cost of accessing the registry, including any arrangement with any telemarketer or service provider to divide the costs to access the registry among various clients of that telemarketer or service provider.

(d) Each person who pays, either directly or through another person, the annual fee set forth in § 310.8(c), each person excepted under § 310.8(c) from paying the annual fee, and each person excepted from paying an annual fee under § 310.4(b)(1)(iii)(B), will be provided a unique account number that will allow that person to access the registry data for the selected area codes at any time for the twelve month period beginning on the first day of the month in which the person paid the fee ("the annual period"). To obtain access to additional area codes of data during the first six months of the annual period, each person required to pay the fee under § 310.8(c) must first pay \$54 for each additional area code of data not initially selected. To obtain access to additional area codes of data during the second six months of the annual period, each person required to pay the fee under § 310.8(c) must first pay \$27 for each additional area code of data not initially selected. The payment of the additional fee will permit the person to access the additional area codes of data for the remainder of the annual period.

\* \* \* \* \*

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. E8-17064 Filed 7-24-08; 8:45 am]

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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1310**

[Docket No. DEA-299F]

RIN 1117-AB12

**Control of a Chemical Precursor Used in the Illicit Manufacture of Fentanyl as a List I Chemical**

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

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is finalizing the

Interim Rule with Request for Comment published in the **Federal Register** on April 23, 2007. The Interim Rule controlled the chemical N-phenethyl-4-piperidone (NPP) as a List I chemical under the Controlled Substances Act. Clandestine laboratories are using this chemical to illicitly manufacture the schedule II controlled substance fentanyl. No comments to the Interim Rule were received. This Final Rule finalizes the regulations without change.

**DATES:** *Effective Date:* July 25, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Christine A. Sannerud, PhD., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152 at (202) 307-7183.

**SUPPLEMENTARY INFORMATION:**

**Background**

On April 23, 2007 (72 FR 20039), the Drug Enforcement Administration (DEA) published an Interim Rule with Request for Comment which established regulations controlling the chemical N-phenethyl-4-piperidone (NPP) as a List I chemical under the Controlled Substances Act (CSA). This action was taken because DEA was extremely concerned with the increase in the illicit manufacture and distribution of fentanyl, which resulted in more than 1,000 confirmed or suspected fentanyl-related overdoses and fentanyl-related deaths across the country.

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. However, 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 endpoints being measured, 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. However, fentanyl is a very dangerous substitute for heroin because the amount that produces a euphoric effect also induces respiratory depression. Furthermore, due to fentanyl's increased potency over heroin, illicit drug dealers have trouble adjusting ("cutting") pure fentanyl into proper dosage concentrations. As a

result, drug abusers 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 in the amount of fentanyl taken can be, and is often, lethal because the resulting level of respiratory depression is sufficient to cause the user to stop breathing.

In April 2006, DEA issued an officer safety alert regarding the special precautions that must be observed when handling and processing suspected fentanyl. DEA is concerned with the unusual health hazards posed to law enforcement officers and forensic chemists from exposure to high purity fentanyl during law enforcement operations. Since high purity fentanyl can be fatal if sub-milligram quantities are accidentally swallowed, inhaled, or absorbed through the skin, the potential for lethal fentanyl exposure to law enforcement officers and chemists exists during raids of fentanyl clandestine laboratories, during seizures of drug exhibits, and during subsequent testing of pure fentanyl in the forensic laboratories.

**Illicit Manufacture of Fentanyl**

As discussed extensively in the Interim Rule with Request for Comment, DEA determined from the forensic testing of seized illicit fentanyl that the chemical NPP was being used to illicitly manufacture fentanyl. Since 2000, four of the five domestic fentanyl clandestine laboratories seized by law enforcement have used NPP as starting material to manufacture the illicit fentanyl. From these four domestic clandestine laboratories, about 800 grams equivalent of pure fentanyl were seized. Furthermore, enough of the unused NPP precursor chemical was also seized to make an additional 5,000 grams of pure fentanyl. Therefore, from the amount of illicit fentanyl and precursor chemicals found at these four domestic fentanyl laboratories, the laboratories could have potentially 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.

Three of the domestic fentanyl clandestine laboratories seized by law enforcement are known to have obtained the NPP precursor chemical from domestic suppliers. The Interim Rule made the purchase of NPP from domestic or international suppliers a regulated transaction. In this way, DEA will be informed of the sale of NPP and can take appropriate action, if necessary. Thus, DEA regulated the

chemical NPP as a List I chemical under the CSA (21 U.S.C. 801 *et seq.*). Furthermore, under 21 U.S.C § 811(e) of the CSA, DEA also intends to control ANPP as a schedule II immediate precursor to fentanyl under a separate rulemaking.

**Illicit Fentanyl-Related Deaths**

The distribution of illicit fentanyl or illicit fentanyl combined with heroin or cocaine has resulted in an outbreak of more than 1,000 confirmed or suspected fentanyl-related overdoses and fentanyl-related deaths across the country according to the Centers for Disease Control and Prevention (CDC) and local medical examiners. 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. As discussed in the Interim Rule with Request for Comment, from the information and data collected, there is strong indication that the fentanyl in these confirmed and suspected fentanyl-related deaths is illicitly manufactured rather than diverted from legal pharmaceutical manufacturers. The current forensic data suggests that most of these fentanyl-related deaths are from fentanyl illicitly manufactured using NPP.

**Availability of the Precursor Chemical**

DEA determined that the precursor chemical, NPP, is readily available from commercial chemical suppliers. DEA identified at least 62 suppliers of NPP, of which 14 are located domestically and 48 are located internationally in Germany, India, and China. Since 2000, law enforcement has evidence to support that the NPP precursor chemical was obtained from domestic suppliers for three domestic fentanyl clandestine laboratories. Further, a fentanyl clandestine laboratory in Mexico is believed to have obtained the NPP precursor chemical from an international supplier. Law enforcement identified four separate chemical suppliers that have distributed NPP to illicit fentanyl clandestine laboratories.

**Regulation of NPP as a List I Chemical**

Based on the above, on April 23, 2007, DEA published an Interim Rule with Request for Comment (72 FR 20039) controlling NPP as a List I chemical. That rule made the domestic sale of NPP a regulated transaction. That rule also made the importation of NPP from an international supplier a regulated transaction. Documenting the domestic sale and importation of NPP is needed by law enforcement to identify

the domestic diversion of NPP for the illicit manufacture of fentanyl in the United States. Finally, that rule specified that chemical mixtures containing NPP were not exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by a NPP manufacturer and the application is reviewed and accepted by DEA under 21 CFR 1310.13.

#### Comments Received

DEA did not receive any comments to its Interim Rule with Request for Comment (72 FR 20039, April 23, 2007) controlling NPP as a List I chemical and regulating all chemical mixtures containing NPP. Therefore, DEA is hereby finalizing that Interim Final Rule without change.

#### Regulatory Certifications

*Administrative Procedure Act (5 U.S.C. 553)*

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including making the rule effective upon the date of publication. DEA finds good cause to make this rule effective upon publication, as this Final Rule merely confirms existing regulatory requirements implemented as part of the Interim Rule with Request for Comment published April 23, 2007, at 72 FR 20039.

*Regulatory Flexibility Act and Small Business Concerns*

The Acting Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)).

Some of the firms DEA identified as potentially handling NPP are small entities. The highest cost that the rule would impose on these firms is less than \$2,500 for registration. The smallest firm (1 to 4 employees) in the organic chemical sector has annual revenues of about \$1.1 million. For those not already registered with DEA, the cost of registration represents 0.2 percent of annual revenues, which does not constitute a significant economic impact. DEA did not receive any comments to its Interim Rule controlling NPP as a List I chemical. Therefore, the Acting Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

*Executive Order 12866*

The Acting Administrator certifies that this rulemaking has been drafted in accordance with the principles in

Executive Order 12866 Section 1(b). It has been determined that this is "not a significant regulatory action." Therefore, this action has not been reviewed by the Office of Management and Budget.

*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.

*Paperwork Reduction Act*

With publication of the Interim Final Rule controlling NPP as a List I chemical (72 FR 20039), persons handling NPP became subject to CSA List I regulatory requirements. Any person who manufactures, distributes, imports, or exports NPP must register with DEA. As discussed in the Interim Rule, DEA has identified 14 domestic chemical companies who would be required to register with DEA if they continued to handle NPP. Persons wishing to register with DEA to handle List I chemicals must do so using DEA Form 510, Application for Registration under Domestic Chemical Diversion Control Act of 1993, and persons wishing to renew their registration must do so using DEA Form 510a, Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993 [OMB control # 1117-0031]. With publication of the Interim Rule, DEA received approval from the Office of Management and Budget to revise this information collection as discussed above.

Persons importing, exporting, and conducting international transactions involving NPP must comply with regulatory requirements regarding the notification of DEA of pending transactions. As DEA had no information on which to estimate how many of the 14 identified firms import, export, or conduct international transactions with NPP, DEA estimated that all identified firms conduct such transactions. DEA estimated that each firm will conduct five import transactions and two export transactions annually. DEA did not identify any firms serving as United States brokers conducting international transactions

involving NPP. Therefore, DEA did not estimate any international transactions involving NPP. Persons importing, exporting, and conducting international transactions involving List I chemicals report those transactions to DEA on DEA Form 486, Import/Export Declaration for List I and List II chemicals [OMB control # 1117-0023]. With publication of the Interim Rule, DEA received approval from the Office of Management and Budget to revise this information collection as discussed above.

*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 were 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 Congressional Review Act/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 1310

Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

#### Adoption as Final Rule

■ The Interim Rule amending part 1310 of Title 21, of the Code of Federal Regulations, which published in the **Federal Register** on April 23, 2007 at 72 FR 20039, is hereby adopted as a Final Rule without change.

Dated: July 17, 2008.

**Michele M. Leonhart**,  
Acting Administrator.

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