

monkfish, skates, Atlantic mackerel, squid, butterfish, scup, black sea bass, bluefish, spiny dogfish, Atlantic herring, tilefish, or Atlantic deep-sea red crab; or a moratorium permit for summer flounder; to carry a NMFS-approved sea sampler/observer. Also, any vessel or vessel owner/operator that fishes for, catches or lands hagfish, or intends to fish for, catch, or land hagfish in or from the exclusive economic zone must carry a NMFS-approved sea sampler/observer when requested by the Regional Administrator in accordance with the requirements of this section.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1310

[Docket No. DEA-299I]

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), U.S. Department of Justice.

**ACTION:** Interim rule with request for comments.

**SUMMARY:** This rulemaking controls the chemical N-phenethyl-4-piperidone (NPP) as a List I chemical under the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). Clandestine laboratories are using this chemical to illicitly manufacture the schedule II controlled substance fentanyl.

The recent distribution of illicitly manufactured fentanyl has caused an unprecedented outbreak of hundreds of suspected fentanyl-related overdoses, at least 972 confirmed fentanyl-related deaths, and 162 suspected fentanyl-related deaths occurring mostly in Delaware, Illinois, Maryland, Michigan, Missouri, New Jersey, and Pennsylvania. NPP has been identified as the starting material in several seized fentanyl clandestine laboratories. In addition to DEA's concern regarding the deaths associated with illicitly manufactured fentanyl, DEA is extremely concerned about the safety of law enforcement officers encountering these clandestine laboratories. Therefore, DEA is regulating NPP as a List I chemical through this Interim Rulemaking. DEA is soliciting comments on this Interim Rule.

This rulemaking will subject handlers of NPP to the chemical regulatory provisions of the CSA and its implementing regulations, including 21 CFR Parts 1309, 1310, 1313, and 1316. This rulemaking does not establish a threshold for domestic and international transactions of NPP. As such, all transactions involving NPP, regardless of size, shall be regulated. This rulemaking also specifies that chemical mixtures containing NPP will not be exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of NPP will be regulated and will be subject to control under the CSA.

**DATES:** This rulemaking will become effective on April 23, 2007. Persons seeking registration must apply on or before June 22, 2007 to continue their business pending final action by DEA on their application.

Written comments must be postmarked, and electronic comments must be sent on or before June 22, 2007.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-299I" 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, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent directly to DEA electronically by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto: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 only. DEA will not accept any file formats other than those specifically listed here.

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

**SUPPLEMENTARY INFORMATION:**

## Background

The DEA is extremely concerned with the increase in the illicit manufacture and distribution of fentanyl, which has resulted in hundreds of 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, unsuspecting heroin users or heroin users who know the substance contains fentanyl have difficulty determining how much to take to get their "high" and 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 exists during raids of fentanyl clandestine laboratories, during seizures of drug exhibits, and during subsequent testing of pure fentanyl in the forensic laboratories. The

primary lethal exposure routes from high purity fentanyl are the following: accidental inhalation of airborne fentanyl powder; accidental transfer of fentanyl powder/liquid from contaminated hands/gloves that inadvertently touch the mouth, nose, or other mucous membranes; and accidental transfer through cuts in the skin or roughly abraded skin.

#### Illicit Manufacture of Fentanyl

DEA has determined from the forensic testing of seized illicit fentanyl that both the Janssen synthesis route and the Siegfried method are being used to clandestinely produce fentanyl. In 1965, Janssen Pharmaceutical patented the original synthesis procedure for fentanyl, which used *n*-benzyl-4-piperidone as the starting material. 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 fentanyl synthesis route was published in the scientific literature that uses NPP as the starting material. The Chemical Abstracts Service Registry Number<sup>1</sup> (CASRN) for NPP is 39742-60-4. The NPP synthesis route is described on the Internet and is referred to as the Siegfried method. 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 (*i.e.*, a small amount of ANPP is not consumed in the last reaction in the synthesis and a trace amount of ANPP can be found in the illicit fentanyl produced).

Since 2000, four of the five domestic fentanyl clandestine laboratories seized by law enforcement have used the

Siegfried method or a modified version of the Siegfried method 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 using the Siegfried method or modified Siegfried method, 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. This rule will make 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 is regulating 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

DEA has seen a recent increase in the illicit manufacture of fentanyl. In just the last three years, a total of four domestic fentanyl clandestine laboratories have been seized. Furthermore, in 2006, DEA saw a sharp increase in the seizures of illicit fentanyl. Law enforcement seized a one kilogram package of high purity illicitly-manufactured fentanyl hydrochloride in California, a variety of illicit tablets containing fentanyl whose appearance is designed to mimic Ecstasy and OxyContin® tablets, and various mixtures of illicitly-manufactured fentanyl powders combined with heroin or cocaine from locations across the United States.

The distribution of illicit fentanyl or illicit fentanyl combined with heroin or cocaine (*i.e.*, a "speedball") has resulted in an outbreak of hundreds of suspected fentanyl-related overdoses, at least 972

confirmed fentanyl-related deaths, and 162 suspected fentanyl-related deaths occurring mostly in Delaware, Illinois, Maryland, Michigan, Missouri, New Jersey, and Pennsylvania 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.

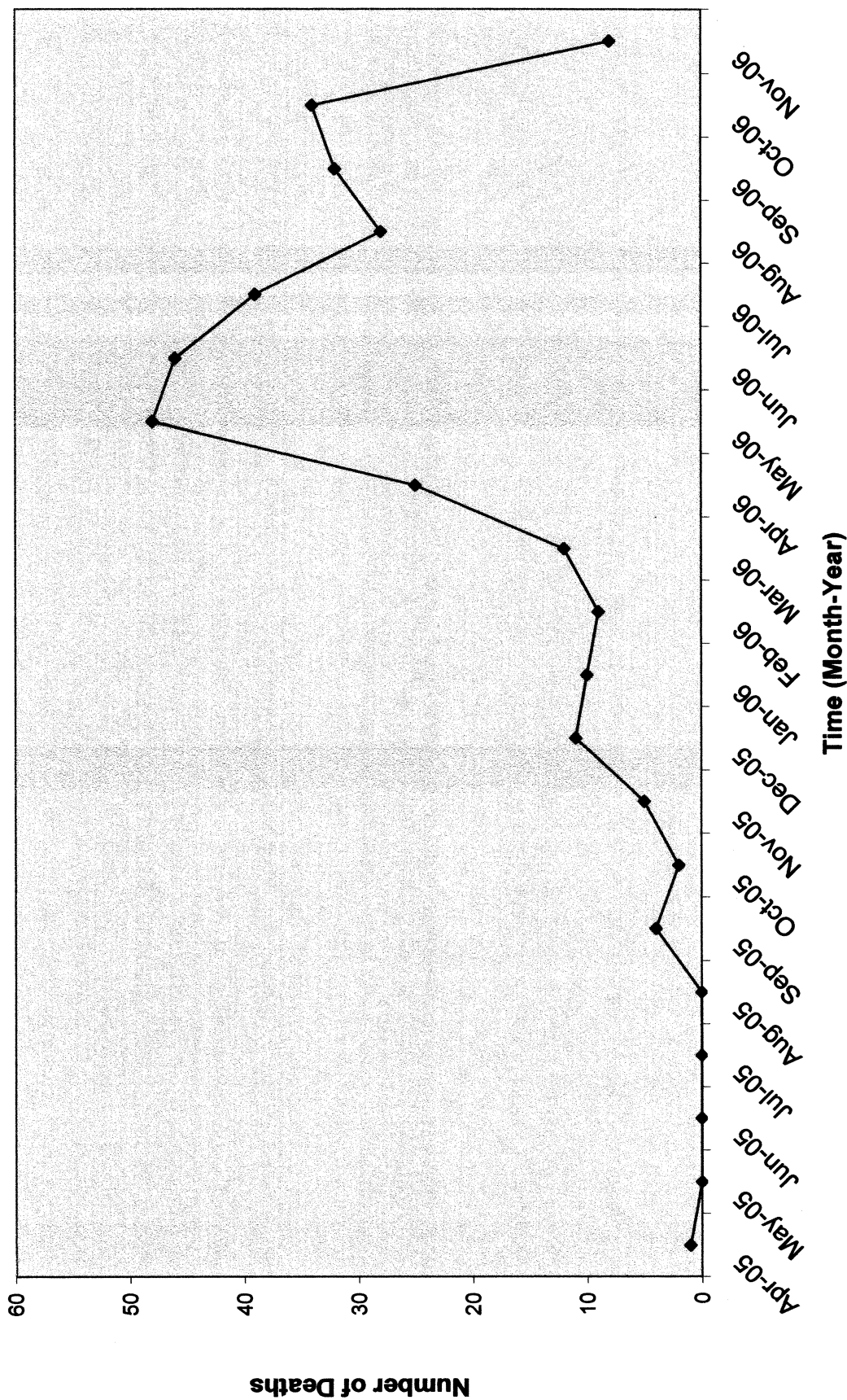
Confirmed illicit fentanyl-related deaths have been reported to the DEA for the following six jurisdictions: Philadelphia, Pennsylvania; Cook County, Illinois; Wayne County, Michigan; St. Louis County, Missouri; the entire state of New Jersey, and the entire state of Delaware. Between April 13, 2006, and September 27, 2006, the Philadelphia Medical Examiner's Office confirmed 179 fentanyl-related deaths. Between April 18, 2005, and November 9, 2006, the Chief Medical Examiner of Cook County, Illinois confirmed 314 fentanyl-related deaths in the city of Chicago and its suburbs. Between August 27, 2005, and December 31, 2006, the Wayne County Medical Examiner confirmed 230 fentanyl-related deaths in the city of Detroit and the surrounding county. Between August 16, 2005, and August 28, 2006, the St. Louis Medical Examiner confirmed 33 fentanyl-related deaths in St. Louis County. Between January 25, 2006, and September 21, 2006, the New Jersey Department of Health confirmed 86 fentanyl-related deaths in the entire State of New Jersey. Between April 20, 2006, and September 2, 2006, the Chief Medical Examiner for Wilmington, Delaware, confirmed 19 fentanyl-related deaths in the entire state of Delaware. Since autopsies and toxicological testing for fentanyl take several weeks to complete and report, the above medical examiner reports represent the most current information regarding confirmed deaths linked to fentanyl available to DEA.

The graph below shows the monthly rate of fentanyl-related deaths in the city of Chicago and its suburbs (Cook County, Illinois) through the beginning of November 2006. The rapid onset of the illicit fentanyl outbreak can be observed in the graph.

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<sup>1</sup> 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 CAS registry number provides consistent and unambiguous identification of chemicals and facilitates sharing of chemical information.

**Monthly Fentanyl-Related Deaths in Cook County, IL**



Beyond these 972 confirmed fentanyl-related deaths in the six jurisdictions outlined above, other areas of the country have also been significantly impacted by this problem. There are 162 suspected fentanyl-related deaths in these areas:

- Grundy County, Illinois.
- Macomb, Oakland & Genesee Counties of Michigan.
- Rest of Pennsylvania.
- Maryland, Massachusetts, Virginia, New Hampshire, Maine, Kentucky, and Ohio.

From the information and data collected, there is a strong indication that the fentanyl in these confirmed and suspected fentanyl-related deaths is illicitly manufactured rather than diverted from legal pharmaceutical manufacturers. Deaths related to fentanyl pharmaceutical products were eliminated from the fentanyl-related deaths reported to the DEA by both the Cook County and Philadelphia medical examiners. Furthermore, forensic testing of seized fentanyl drug exhibits has identified the illicit fentanyl impurities benzylfentanyl and/or ANPP in the majority of these exhibits. The current forensic data suggests that most of these fentanyl-related deaths are from fentanyl illicitly manufactured by the Siegfried method using NPP.

#### Availability of the Precursor Chemical

DEA has determined that the precursor chemical, NPP, is readily available from commercial chemical suppliers. DEA has 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. Furthermore, a fentanyl clandestine laboratory in Mexico is believed to have obtained the NPP precursor chemical from an international supplier. Law enforcement has identified four separate chemical suppliers that have distributed NPP to illicit fentanyl clandestine laboratories. This rule will make the domestic sale of NPP a regulated transaction. This rule will also make 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.

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

The CSA, specifically 21 U.S.C. 802(34), 21 U.S.C. 802(35), and its implementing regulations at 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, additional precursor or essential chemicals as "listed chemicals" if they are used in the manufacture of controlled substances in violation of the CSA. NPP is being used by clandestine laboratories as the starting material for the illicit manufacture of fentanyl. This interim rule regulates NPP as a List I chemical because DEA finds that NPP is used in the illicit manufacture of the controlled substance fentanyl and is important to the illicit manufacture of the controlled substance fentanyl.

Handlers of NPP will become subject to the chemical regulatory provisions of the CSA, including 21 CFR Parts 1309, 1310, 1313, and 1316. This rulemaking does not establish a threshold for domestic and import transactions of NPP pursuant to the provisions of 21 CFR 1310.04(g). Due to the high potency of fentanyl, even a single gram (*i.e.*, 1/28th of an ounce) of NPP can be used illicitly to make about 7,750 dosage units of fentanyl. Therefore, all NPP transactions regardless of size shall be regulated transactions as defined in 21 CFR 1300.02(b)(28). As such, all NPP transactions will be subject to recordkeeping, annual manufacturer reporting of inventory and use data, import/export controls, and other CSA chemical regulatory requirements.

#### Chemical Mixtures of NPP

This rulemaking also specifies that chemical mixtures containing NPP will not be 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 the DEA under 21 CFR 1310.13 (Exemption by Application Process). Since even a small amount of NPP is able to make a significant amount of fentanyl, the control of chemical mixtures containing any amount of NPP is necessary to prevent the illicit extraction, isolation, and use of the NPP. Therefore, all chemical mixtures containing any quantity of NPP will be subject to CSA control, unless the NPP manufacturer is granted an exemption by the application process discussed below. This interim rule modifies the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of NPP are

subject to CSA chemical control provisions.

#### Exemption by Application Process

DEA has implemented an application process to exempt mixtures from the requirements of the CSA and its implementing regulations (21 CFR 1310.13). This application process was finalized in the Final Rule (68 FR 23195) published May 1, 2003. Under the application process, manufacturers may submit an application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical cannot be readily recovered (*i.e.*, it meets the conditions in 21 U.S.C. 802(39)(A)(vi)).

#### Requirements for Handling List I Chemicals

The designation of NPP as a List I chemical will subject NPP handlers to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of a List I chemical. Persons potentially handling NPP, including regulated chemical mixtures containing NPP, will be required to comply with the following List I chemical regulations:

1. *Registration.* Any person who manufactures or distributes a List I chemical, or proposes to engage in the manufacture or distribution of a List I chemical, must obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for List I chemical handlers are set forth in 21 CFR Part 1309.

Consistent with 21 CFR Parts 1309 and 1310, separate registrations will be required for manufacturing, distribution, importing, and exporting of NPP. Different locations operated by a single entity require separate registration if any location is involved with the distribution, importation, or exportation of NPP. Further, a separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed, imported, or exported by a person (21 CFR 1309.23). Any person distributing, importing, or exporting an NPP chemical mixture will be subject to the registration requirement under the CSA as well.

Effective April 23, 2007, any person manufacturing, distributing, importing, or exporting NPP or a chemical mixture containing NPP will become subject to the registration requirement under the

CSA. DEA recognizes, however, that it is not possible for persons who are newly subject to the registration requirement to complete and submit an application for registration and for DEA to issue registrations for those activities immediately. Therefore, to allow continued legitimate commerce, DEA is establishing in § 1310.09(h) a temporary exemption from the registration requirement for persons desiring to engage in the manufacture, distribution, importation, or exportation of NPP, provided that DEA receives a properly completed application for registration on or before June 22, 2007. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or on their application for exemption for a chemical mixture containing NPP pursuant to § 1310.13.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, are effective on April 23, 2007. Additionally, the temporary exemption does not suspend applicable Federal criminal laws relating to this chemical, nor does it supersede state or local laws or regulations. All manufacturers, distributors, importers, and exporters of NPP or chemical mixtures containing NPP must comply with applicable state and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* The CSA (21 U.S.C. 830) requires that certain records be kept and reports be made with respect to listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR Part 1310. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical will be required to submit manufacturing, inventory and use data on an annual basis (21 CFR 1310.05(d)). Existing standard industry reports containing the required information will be acceptable, provided the information is readily retrievable from the report.

Title 21 CFR 1310.05(a) requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA and its corresponding regulations.

3. *Import/Export.* All imports/exports of a listed chemical shall comply with the CSA import and export provisions including 21 U.S.C. 957 and 971. Regulations for importation and exportation of List I chemicals are described in 21 CFR Part 1313.

4. *Security.* All applicants and registrants shall provide effective controls against theft and diversion of chemicals as described in 21 CFR 1309.71.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of a regulated chemical/chemical mixture or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR 1316 Subpart A.

#### **Justification for Interim Rulemaking**

Under 5 U.S.C. 553(b)(B), an agency may forgo a Notice of Proposed Rulemaking and the accompanying period of public comment where “the agency for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” DEA is implementing these controls as an Interim Rule because DEA has determined that the delay necessitated by following public notice and comment procedures would be “contrary to the public interest.”

The public harm caused by the current illicit manufacture and distribution of fentanyl is unprecedented. The higher potency of fentanyl relative to heroin prevents illicit drug dealers from adjusting (“cutting”) pure fentanyl into fixed, predictable, non-lethal dosage concentrations resulting in overdoses and deaths among the heroin user population. The manufacture and distribution of illicit fentanyl has generated a pattern of outbreaks of overdoses and deaths across the United States. Since April 2005, the current outbreak of illicit fentanyl is responsible for at least 972 confirmed fentanyl-related deaths and an additional 162 suspected fentanyl-related deaths. Most of the fentanyl-related deaths have occurred since February 2006 and have occurred mostly in the Chicago, Detroit, and Philadelphia metropolitan areas.

These fentanyl-related deaths are continuing at a sustained rate.

The current volume of deaths is creating a growing crisis for law enforcement and health authorities. In response to the emerging crisis, DEA joined Chicago area law enforcement agencies to convene an emergency two-day conference on fentanyl in Chicago in June 2006 and the Office of National Drug Control Policy (ONDCP) convened a one-day demand reduction forum in Philadelphia in July 2006. Numerous law enforcement and health authorities expressed concern regarding recent increases in clandestine production of fentanyl and the resulting overdoses and deaths. The testing of drug exhibits by Federal, State, and local forensic laboratories confirms that the bulk of the fentanyl being distributed in the outbreak areas has been manufactured illicitly. Furthermore, the lack of a sudden increase in the diversion of fentanyl-containing pharmaceutical products supports the conclusion that the current outbreak of fentanyl-related deaths is from illicitly manufactured 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 indicates that the majority of the deaths in the current fentanyl outbreak have been caused by the distribution of illicit fentanyl that was made by the Siegfried method. This determination is based on the identification of ANPP and the absence of the benzylfentanyl impurity in seized fentanyl drug exhibits. The starting material for the Siegfried method, NPP, is currently unregulated and readily available from both domestic and international chemical supply companies.

Immediate action at the Federal level is warranted to prevent the unregulated manufacture, importation, exportation, and distribution of the NPP precursor chemical. DEA, as well as other law enforcement and public health authorities, have concluded that this action is necessary to prevent any further domestic illicit production of fentanyl. Law enforcement has postulated that many of the fentanyl-related overdoses and deaths in the Chicago and Detroit areas may be associated with a clandestine fentanyl laboratory recently seized in Mexico. However, a significant number of the fentanyl-related overdoses and deaths may also be associated with domestic clandestine fentanyl laboratories. Control of NPP will aid DEA's efforts to combat domestic production of illicit

fentanyl by enabling DEA to track NPP from its importation through all domestic transactions. Furthermore, the regulatory controls on the exportation of NPP to potential source countries will help DEA prevent the use of NPP exported from the United States for the foreign production of illicit fentanyl.

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 exists during raids of fentanyl clandestine laboratories, during seizures of drug exhibits, and during subsequent testing of pure fentanyl in the forensic laboratories. The primary lethal exposure routes from high purity fentanyl are the following: Accidental inhalation of airborne fentanyl powder; accidental transfer of fentanyl powder/liquid from contaminated hands/gloves that inadvertently touch the mouth, nose, or other mucous membranes; and accidental transfer through cuts in the skin or roughly abraded skin.

Another reason DEA is issuing the regulation of NPP as an Interim Rule is to prevent illicit fentanyl manufacturers from stockpiling NPP. A Notice of Proposed Rulemaking would provide advance warning to illicit fentanyl manufacturers of DEA's intent to control NPP. The illicit fentanyl manufacturers could easily stockpile multiple kilograms of NPP undetected before the chemical becomes regulated. Due to the potency of fentanyl, the stockpiling of as little as 10 kilograms of NPP is sufficient to cause another outbreak of fentanyl-related deaths of the unprecedented magnitude the U.S. is currently experiencing.

The Administrative Procedure Act permits an agency to forgo the delay in effective date associated with substantive rules "for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). For the same reasons discussed above, in order to protect the public health and prevent further illicit production of fentanyl, this rule shall be effective immediately upon publication. Furthermore, pursuant to its authority under 21 U.S.C. 821 and 871, DEA has concluded that the threat to public health and safety is such that it is necessary and appropriate for DEA to

forgo the requirements of 21 CFR 1310.02(c) that the agency publish a proposal 30 days prior to adding a listed chemical by final rule.

#### **Handling of Confidential or Proprietary Information**

Confidential or proprietary information may be submitted as part of a comment regarding this Interim Rulemaking. Confidential or proprietary information should be clearly identified at the beginning of the comment. Information designated as confidential or proprietary will be treated accordingly. The release of confidential business information is protected from disclosure by Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4), and the U.S. Department of Justice procedures set forth in 28 CFR 16.8. Comments may be submitted using the information provided in the **ADDRESSES** section of this document, and must be postmarked on or before June 22, 2007.

#### **Regulatory Certifications**

##### *Regulatory Flexibility Act and Small Business Concerns*

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)). The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment. DEA is issuing this rule as an emergency action and an interim final rule. Therefore, the RFA provisions do not apply. DEA did consider, however, the impact on small entities.

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. Consequently, this rule will not have a significant economic impact on a substantial number of 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 listing NPP as a List I chemical. Anyone manufacturing, distributing, importing, or exporting NPP will have to register each location where NPP is handled, maintain records of transactions involving NPP, and take steps to ensure that the chemicals are secure (e.g., stored in sealed containers in areas where access can be controlled or monitored). The requirement for records of transactions can be met using routine business records (e.g., purchase orders, shipping papers).

DEA has identified 14 domestic chemical companies that supply NPP and that would be required to comply with this rule. Furthermore, DEA has determined that the vast majority of the domestic use of NPP is for the manufacture of the schedule II drug fentanyl. Eight companies may domestically manufacture NPP, of which two of these companies may also import NPP. However, DEA has not been able to determine whether these companies are currently manufacturing NPP. Some companies may not manufacture NPP, but rather purchase NPP in order to redistribute it to meet special orders. Other companies may manufacture NPP upon receiving an order; one company indicated that it has not produced NPP for two years. DEA has identified an additional six domestic companies that appear to only import NPP for subsequent domestic distribution. DEA has been able to document one domestic pharmaceutical company that uses NPP to manufacture fentanyl or fentanyl analogues.

The cost of compliance with the chemical requirements is basically the cost of the annual registration fee (\$2,430 for manufacturers; \$1,215 for distributors, importers, and exporters) plus the time required to complete the registration form (0.5 hours); registrations can be completed online. The recordkeeping requirements can be met with normal business records. The FDA requirements for manufacturing practices for pharmaceutical ingredients, together with the value of the products, generally ensure that firms already have security measures adequate to meet DEA's requirements. Even if the two firms that could manufacture or import obtained separate registrations for the two business activities, the total cost of the rule would be less than \$30,000, which is the rounded estimate of the cost for all fourteen firms to register with DEA in their respective business activities.

##### *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*

This Interim Rulemaking will subject persons handling NPP to CSA List I regulatory requirements. Any person who manufactures, distributes, imports, or exports NPP must register with DEA. As discussed previously, DEA has identified 14 domestic chemical companies who would be required to register with DEA. 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].

Persons importing, exporting, and conducting international transactions involving NPP must comply with regulatory requirements regarding the notification of DEA of pending transactions. As DEA cannot estimate how many of the 14 identified firms import, export, or conduct international transactions with NPP, DEA is estimating that all identified firms conduct such transactions. DEA has no information regarding actual number of transactions conducted annually, but based on the uses of NPP believes that the number of transactions is very low. DEA is estimating that each firm will conduct five import transactions, and two export transactions annually. DEA has not identified any firms serving as United States brokers conducting

international transactions involving NPP. Therefore, DEA has not estimated any international transactions involving NPP.

The U.S. Department of Justice, Drug Enforcement Administration, has submitted the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The information collections are published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the collections of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Overview of Information Collections 1117-0031:*

- (1) *Type of Information Collection:* Revision of an existing collection.
- (2) *Title of the Form/Collection:* Application for Registration under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993.

(3) *Agency form number, if any, and the applicable component of the U.S. Department of Justice sponsoring the collection:*

*Form Number:* DEA Form 510 and DEA Form 510a.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* Business or other for-profit.

*Other:* Not-for-profit, government agencies.

*Abstract:* The Domestic Chemical Diversion Control Act requires that manufacturers, distributors, importers, and exporters of List I chemicals which may be diverted in the United States for the production of illicit drugs must register with DEA. Registration provides a system to aid in the tracking of the distribution of List I chemicals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* DEA estimates that 2,301 persons respond to this collection annually. DEA estimates that it takes 30 minutes for an average respondent to respond when completing the application on paper, and 15 minutes for an average respondent to respond when completing an application electronically. This application is submitted annually.

(6) *An estimate of the total public burden (in hours) associated with the collection:* DEA estimates that this collection has a public burden of 783 hours annually.

Form	Number respondents	Total burden hours
DEA-510 (paper) .....	187	93.5
DEA-510 (electronic) .....	102	25.5
DEA-510a (paper) .....	644	322
DEA-510a (electronic) .....	1,368	342
Total .....	.....	783

*Overview of Information Collection 1117-0023:*

- (1) *Type of Information Collection:* Revision of an existing collection.
- (2) *Title of the Form/Collection:* Import/Export Declaration for List I and List II Chemicals.
- (3) *Agency form number, if any, and the applicable component of the U.S. Department of Justice sponsoring the collection:*  
Form Number: DEA Form 486.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.  
 (4) *Affected public who will be asked or required to respond, as well as a brief abstract:*  
*Primary:* Business or other for-profit.  
*Other:* None.  
*Abstract:* Persons importing, exporting, and conducting international transactions with List I and List II chemicals must notify DEA of those transactions in advance of their occurrence, including information

regarding the person(s) to whom the chemical will be transferred and the quantity to be transferred. For importations, persons must also provide return declarations, confirming the date of the importation and transfer, and the amounts of the chemical transferred. This information is used to prevent shipments not intended for legitimate purposes.  
 (5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

	Number of respondents	Number of responses	Average time per response	Total hours
Form 486 (export) .....	239	7,945	0.2 hour (12 minutes) .....	1,589
Form 486 (export return declaration) .....	239	7,945	0.08 hour (5 minutes) .....	662.08
Form 486 (import) .....	230	2,348	0.25 hour (15 minutes) .....	587
Form 486 (import return declaration)* .....	230	2,583	0.08 hour (5 minutes) .....	215.2
Form 486 (international transaction) .....	9	111	0.2 hour (12 minutes) .....	22.2
Form 486 (international transaction return declaration) .....	9	111	0.08 hour (5 minutes) .....	9.25
Quarterly reports for imports of acetone, 2-butanone, and toluene.	110	440	0.5 hour (30 minutes) .....	220
<b>Total</b> .....	<b>239</b>	.....	.....	<b>3,304.73</b>

\*DEA assumes 10% of all imports will not be transferred in the first thirty days and will necessitate submission of a subsequent return declaration.

(6) *An estimate of the total public burden (in hours) associated with the collection:* DEA estimates that this collection will take 3,305 hours annually.  
 If additional information is required, contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, U.S. Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

*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 \$114,000,000 or more 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 21 CFR Part 1310**

Drug traffic control, List I and List II chemicals, reporting requirements.

■ For the reasons set out above, 21 CFR Part 1310 is amended as follows:

**PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES**

■ 1. The authority citation for part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 2. Section 1310.02 is amended by adding a new paragraph (a)(28) to read as follows:

**§ 1310.02 Substances covered.**

\* \* \* \* \*  
 (a) \* \* \*  
 (28) N-phenethyl-4-piperidone (NPP)—8332.  
 \* \* \* \* \*

■ 3. Section 1310.04 is amended by adding a new paragraph (g)(1)(vi) to read as follows:

**§ 1310.04 Maintenance of records.**

\* \* \* \* \*  
 (g) \* \* \*  
 (1) \* \* \*

(vi) N-phenethyl-4-piperidone (NPP)  
 \* \* \* \* \*

■ 4. Section 1310.09 is amended by adding new paragraph (h) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(h) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated N-phenethyl-4-piperidone (NPP), including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing NPP pursuant to § 1310.13 on or before June 22, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports or exports a chemical mixture containing N-phenethyl-4-piperidone (NPP) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A



temporary exemption from the registration requirement will also be provided for those persons whose application for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the

application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

■ 5. Section 1310.12 is amended by adding in alphabetical order in the table

in paragraph (c) an entry for “N-phenethyl-4-piperidone (NPP)” to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \* \*  
(c) \* \* \*

TABLE OF CONCENTRATION LIMITS

	DEA chemical code No.	Concentration	Special conditions
N-phenethyl-4-piperidone (NPP) .....	8332 .....	Not exempt at any concentration .....	Chemical mixtures containing any amount of NPP are not exempt.

\* \* \* \* \*

Dated: April 11, 2007.  
**Michele M. Leonhart,**  
*Deputy Administrator.*  
 [FR Doc. 07–2015 Filed 4–20–07; 8:45 am]  
**BILLING CODE 4410–09–C**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[CGD13–07–013]

RIN 1625–AA00

**Special Local Regulation: ULHRA Hydroplane Races, Columbia Park, Kennewick, WA**

**AGENCY:** Coast Guard, DHS.  
**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary special local regulation for the ULHRA National Series Hydroplane Race to be held on the waters of the Columbia River in the vicinity of Columbia Park, Kennewick, WA. These special local regulations limit the movement of non-participating vessels in the regulated race area. This temporary rule is needed to provide for the safety of life on navigable waters during the event.

**DATES:** This regulation is effective from 7 a.m. to 7 p.m. on May 19 and 20, 2007.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket (CGD13–07–013) and are available for inspection or copying at U.S. Coast Guard MSO/ Group Portland, 6767 N. Basin Avenue, Portland, Oregon 97217 between 7 a.m.

and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Petty Officer Michelle Duty, c/o Captain of the Port, Portland 6767 N. Basin Avenue, Portland, Oregon 97217, (503) 240–2590.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553 (d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing an NPRM would be contrary to public interest since immediate action is necessary to ensure the safety of vessels and spectators. If normal notice and comment procedures were followed, this rule would not become effective until after the date of the event. For this reason, following normal rulemaking procedures in this case would be impracticable and contrary to the public interest.

**Background and Purpose**

The Coast Guard is establishing a temporary special local regulation to allow for a safe racing event. This event occurs on the Columbia River in Lake Wallula in the vicinity of Columbia Park in Kennewick, WA and is scheduled to start at 7 a.m. and last until 7 p.m. on May 19 and 20, 2007. This event may result in a number of recreational vessels congregating near the hydroplane races. The hydroplane race poses several dangers to the public including excessive noise, objects falling from any accidents, and hydroplanes racing at high speeds in proximity to other vessels. Accordingly,

the special local regulation is needed to protect watercraft and their occupants from safety hazards associated with the event. This special local regulation will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other federal, state, and local agencies.

**Discussion of Rule**

This temporary rule will create a regulated area to assist in minimizing the inherent dangers associated with hydroplane races. These dangers include, but are not limited to, excessive noise, race craft traveling at high speed in close proximity to one another and to spectator craft, and the risk of airborne objects from any accidents associated with hydroplanes. In the event that hydroplanes require emergency assistance, rescuers must have immediate and unencumbered access to the craft. The Coast Guard, through this action, intends to promote the safety of personnel, vessels, and facilities in the area. Due to these concerns, public safety requires these regulations to provide for the safety of life on the navigable waters.

**Regulatory Evaluation**

This temporary rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this temporary rule to be so minimal