changes that are now in effect. Specifically, section 3052 of the 21st Century Cures Act amended section 520(m) of the FD&C Act to allow for HDE approval for devices that, among other things, treat or diagnose a disease or condition that affects ''not more than 8,000'' individuals in the United States; this threshold had been ''fewer than 4,000'' individuals in the United States (amending 21 U.S.C. 360j(m), *passim*). This final rule amends part 814 (21 CFR part 814) in several places to accurately reflect the threshold recently enacted into law.

In addition, section 3056 of the 21st Century Cures Act amended section 520 of the FD&C Act to remove the requirement for institutional review committees, *i.e.,* IRBs, for devices to be ''local'', (amending 21 U.S.C. 360j, *passim*). This final rule amends 21 CFR 814.124(a), ''IRB approval'', to remove the term ''local'' and related language in order to accurately reflect the requirements recently enacted into law.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only updates the implementing regulation to restate the statute in light of amendments recently enacted into law (see 5 U.S.C. 553(b)(B), relating to notice and comment procedures): ''[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary''. *Gray Panthers Advocacy Committee* v. *Sullivan,* 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also *Komjathy* v. *Nat. Trans. Safety Bd.,* 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule ''does no more than repeat, virtually verbatim, the statutory grant of authority'', notice-and-comment procedures are not required). Therefore, we are issuing these amendments as a final rule, and publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the new requirements are already effective as a matter of law. Furthermore, this rule does not establish additional regulatory obligations or impose additional burden on regulated entities. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for these amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, 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 part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

§ 814.3 [Amended]

■ 2. Amend § 814.3(n) by removing the words ''fewer than 4,000'' and adding in their place the words ''not more than 8,000''.

§ 814.100 [Amended]

■ 3. Amend § 814.100(b) introductory text by removing the words ''fewer than 4,000'' and adding in their place the words ''not more than 8,000''.

§ 814.102 [Amended]

■ 4. Amend § 814.102 as follows:
■ a. In paragraph (a)(5), remove the words ''fewer than 4,000'' in both occurrences and add in their places the words ''not more than 8,000'' for both occurrences;
■ b. In paragraph (b)(3)(i), remove the words ''fewer than 4,000'' and add in their place the words ''not more than 8,000''; and
■ c. In paragraph (b)(3)(ii), remove the words ''4,000 or more'' and add in their place the words ''more than 8,000''.

■ 5. In § 814.124, revise paragraph (a) to read as follows:

§ 814.124 Institutional Review Board requirements.

(a) *IRB approval.* The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having oversight by an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by an IRB. If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by an IRB. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

* * * * *

§ 814.126 [Amended]

■ 6. Amend § 814.126(b)(1)(iii) by removing the number ''4,000'' and adding in its place the number ''8,000''.

Dated: June 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–11816 Filed 6–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–413]

Schedules of Controlled Substances: Placement of Acetyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration will maintain the placement of the substance acetyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act and is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961. This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle, acetyl fentanyl.

DATES: Effective June 7, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control

Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201(d)(1) of the Controlled Substances Act (CSA) (21 U.S.C. 811(d)(1)) states that, if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [section 201(a) (21 U.S.C. 811 (a))] or section [202(b) (21 U.S.C. 812(b)) of the Act] and without regard to the procedures prescribed by [section 201(a) and (b) (21 U.S.C. 811(a) and (b))].'' If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs, 1961, then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control the substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

On May 17, 2016, the Secretary-General of the United Nations advised the Secretary of State of the United States, that during the 59th session of the Commission on Narcotic Drugs, acetyl fentanyl was added to schedule I of the Single Convention on Narcotic Drugs, 1961. This letter was prompted by a decision at the 59th session of the Commission on Narcotic Drugs in March 2016 to schedule acetyl fentanyl under schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control acetyl fentanyl under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

Acetyl Fentanyl

On July 17, 2015, acetyl fentanyl was temporarily placed in schedule I of the CSA in order to avoid an imminent hazard to the public safety (80 FR 42381). Acetyl fentanyl is a potent opioid analgesic and has no accepted medical use in the United States. Since 2013, both law enforcement (DEA's NFLIS and STARLiMS databases) and public health reports demonstrate the unregulated use and distribution of this substance. Law enforcement reports indicate that acetyl fentanyl is available on the illicit market as a powder or in tablet form which mimic pharmaceutical opiate products. In powder form, the identity of the substance may go unknown to the end user as it may be marketed as heroin or mixed with heroin. Recent reports indicate that acetyl fentanyl is available over the Internet.

Acetyl fentanyl exhibits a typical morphine-like profile in animals. Data from the scientific literature show that the analgesic potency of acetyl fentanyl is up to 15.7 times greater than that of morphine in mice as evaluated using an acetic acid writhing method. Since 2013, adverse effects due to acetyl fentanyl toxicity have been reported in humans. Similar to other opioids (*i.e.* heroin, oxycodone, hydrocodone, fentanyl, etc.), acetyl fentanyl induces respiratory depression which may lead to death in an overdose event. DEA is currently aware of at least 57 confirmed fatalities associated with acetyl fentanyl misuse and/or abuse in the United States. The extent of abuse and mortality associated with acetyl fentanyl is likely to be underestimated since it is not included in most drug screens. In addition, the identity of fentanyl and acetyl fentanyl cannot be distinguished by commonly used drug screens including enzyme-linked immunosorbent assay (ELISA). Further confirmatory testing (*i.e.* mass spectrometry) is required to identify acetyl fentanyl.

The DEA is not aware of any claims or any medical or scientific literature suggesting that acetyl fentanyl has a currently accepted medical use in treatment in the United States. In addition, HHS advised the DEA, by letter dated April 29, 2015, that there are no approved new drug applications or investigational new drug applications for acetyl fentanyl.

By letter, dated January 11, 2016, the DEA requested that HHS conduct a scientific and medical evaluation of the substance's medical utility and a scheduling recommendation for acetyl fentanyl. Regardless of this request and any potential response from HHS, the DEA is not required under 21 U.S.C. 811(d)(1) to make any findings required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). Therefore, consistent with the framework of 21 U.S.C. 811(d), DEA concludes that acetyl fentanyl has no currently accepted medical use in treatment in the United States and is most appropriately placed (as it has been since July 2015) in schedule I of the CSA.

Conclusion

In order to meet the obligations of the Single Convention on Narcotic Drugs, 1961 and because acetyl fentanyl has no currently accepted medical use in treatment in the United States, the Administrator of the Drug Enforcement Administration has determined that this substance should remain in schedule I of the Controlled Substances Act.

Requirements for Handling

Acetyl fentanyl has been controlled as a schedule I controlled substance since July 17, 2015. With publication of this final order, acetyl fentanyl remains subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, and conduct of instructional activities with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, acetyl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Acetyl fentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Acetyl fentanyl is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of acetyl fentanyl must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302.

5. *Quota.* A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required in order to manufacture acetyl fentanyl.

6. *Inventory.* Every DEA registrant who possesses any quantity of acetyl fentanyl must keep an inventory of all stocks of this substance on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to acetyl fentanyl pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute acetyl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of acetyl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving acetyl fentanyl not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute ''rule making'' under 5 U.S.C. 551(5), this action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)'s requirement that such action be taken to comply with the United States obligations under the specified international agreements.

Executive Order 12866

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132

This action does not have federalism implications warranting the application of Executive Order 13132. This action does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 13175

This action does not have tribal implications warranting the application of Executive Order 13175. The action does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). However, the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

For the reasons set out above, the DEA amends 21 CFR part 1308 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), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by:

■ i. Redesignating paragraphs (b)(3) through (56) as (b)(4) through (57) and adding a new paragraph (b)(3); and

■ ii. Removing paragraph (h)(4), redesignating paragraphs (h)(5) through (15) as (h)(4) through (14), and adding reserved paragraph (h)(15).

The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(3) Acetyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide)—9821

* * * * *

Dated: May 30, 2017.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2017–11795 Filed 6–6–17; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2015–0399; FRL–9963–25–Region 9]

Air Plan Approval; Nevada, Lake Tahoe; Second 10-Year Carbon Monoxide Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the State of Nevada's (''State'') April 3, 2012 state implementation plan (SIP) submission and the State's August 26, 2016 supplement to their 2012 submittal. The State submitted these two SIP revisions for the Lake Tahoe, Nevada carbon monoxide (CO) area to address the Clean Air Act (CAA) requirement to submit by the eighth year of the first maintenance plan a second 10-year maintenance plan.

DATES: This final rule is effective on July 7, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R09–OAR–2015–0399. All