exercised sufficient operational control to carry out the launch or reentry, § 50919(g) would serve as a bar to FAA licensing the activity.

In the scenarios described above, as currently under development by launch and reentry operators, the NASA astronaut would likely not affect the flight path of the vehicle during a nominal launch. During a launch, the astronaut would likely only manipulate the flight path of the vehicle if an emergency arose. Accordingly, section 50919(g) would not limit a NASA astronaut's ability to engage in operational functions during launch. Most of the conduct or operations would simply constitute the execution of emergency training required of space flight participants by § 460.51.

The analysis for a reentry is similar to that of a launch, with some additional consideration for the possible manual operation of the reentry vehicle by a NASA astronaut. Specifically, a NASA astronaut could initiate reentry manually, but because the scenarios have the reentry operator's flight computer directing the reentry, the NASA astronaut's interaction would not be sufficient to constitute NASA carrying out the reentry. Additionally, the NASA astronaut's exercise of manual control over the vehicle in an off-nominal situation would also not rise to NASA carrying out the reentry because, as discussed above, in an off-nominal situation, the astronaut would largely be implementing procedures created by a commercial launch or reentry operator for purposes of safety or mission success.

In conclusion, Chapter 509 and the FAA's regulations impose no operational constraints on NASA astronauts for the scenarios envisioned here.

Issued in Washington, DC, on November 21, 2013.

Mark W. Bury,

Assistant Chief Counsel for International Law, Legislation and Regulations.

[FR Doc. 2013–28405 Filed 11–29–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–374]

Schedules of Controlled Substances: Placement of Perampanel into Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile], including its salts, isomers, and salts of isomers, into schedule III of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule III controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle perampanel.

DATES: *Effective Date:* January 2, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, but they are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR) parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed. . . .'' Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA, who has further delegated this authority to the Deputy Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of the HHS and on an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule III controlled substances on persons who handle or propose to handle perampanel.

Background

Perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile] is a new chemical entity with central nervous system (CNS)

[1] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1995. In addition, because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''

depressant and hallucinogenic properties. On October 22, 2012, the Food and Drug Administration (FDA) approved a new drug application for perampanel as an adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older. Perampanel will be marketed in the United States under the trade name FYCOMPA®. Perampanel is a non-competitive AMPA (α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid)-type glutamate receptor antagonist. Perampanel was approved in Europe in May 2012 and has been marketed there since July 2012.

HHS and DEA Eight-Factor Analyses

On January 22, 2013, the Assistant Secretary of the HHS provided to the DEA a scientific and medical evaluation and scheduling recommendation entitled ''Basis for the Recommendation for Control of Perampanel and its Salts in Schedule III of the Controlled Substances Act.'' Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that perampanel be controlled in schedule III of the CSA under 21 U.S.C. 812(b). In response, the DEA conducted its own eight-factor analysis of perampanel pursuant to 21 U.S.C. 811(c). Electronic copies of these documents are available at *www.regulations.gov* for easy reference.

Determination to Schedule Perampanel

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Deputy Administrator of the DEA published in the **Federal Register** a notice of proposed rulemaking (NPRM) entitled ''Schedules of Controlled Substances: Placement of Perampanel into Schedule III'' on October 22, 2013 (78 FR 62500), which proposed placement of perampanel in schedule III of the CSA. The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before November 21, 2013. No requests for such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposed rule on or before November 21, 2013.

Comments Received

The DEA received two comments on the proposed rule to schedule perampanel. One commenter was in favor of controlling perampanel as a schedule III controlled substance. Another commenter requested that the DEA make the rule effective on the same date as the publication of the final rule.

Support for the Proposed Rule: One commenter supported controlling perampanel as a schedule III controlled substance, as opposed to a schedule II controlled substance, but expressed concern about the unknown effects and abuse potential of this new drug at higher doses. However, the commenter indicated that the controls applicable to schedule III controlled substances are appropriate until there is more available data on perampanel's effects.

DEA Response: The DEA appreciates the comment in support of this rulemaking.

Request to Change Effective Date: One commenter requested that the DEA make this rule effective on the same date as publication to enable physicians and their patients to have access to perampanel as soon as possible and pointed out that the DEA has included an earlier effective date in the final rule for other drugs including zopiclone, pregablin, and ezogabine.

DEA Response: The DEA appreciates the commenter's request, but does not believe an earlier effective date is warranted. As provided in 21 CFR 1308.45, final orders shall not have an effective date of ''less than 30 days from the date of publication in the **Federal Register** unless the Administrator finds that the conditions of public health or safety necessitate an earlier effective date . . . .'' The Administrator finds that the conditions of public health or safety do not necessitate such an earlier effective date in this instance. There are other anti-seizure medications currently available, specifically lacosamide, an anti-epileptic medication that has a similar clinical indication to perampanel. Though the mechanisms of actions of perampanel and lacosamide are different, the indications are very similar. Like perampanel, lacosamide is indicated as an adjunctive therapy for the treatment of partial-onset seizures, and did not have its 30-day implementation period waived. Furthermore, the DEA believes that providing 30 days for this Final Rule to become effective is expeditious and sufficient to allow handlers to obtain the appropriate registration with the DEA and to comply with regulatory requirements for handling schedule III controlled substances.

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of perampanel. As such, the DEA is scheduling perampanel as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The statute outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(3), finds that:

1. Perampanel has a potential for abuse less than the drugs or other substances in schedules I and II;

2. Perampanel has a currently accepted medical use in treatment in the United States. Perampanel was approved for marketing by the FDA as an adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older; and

3. Abuse of perampanel may lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Deputy Administrator of the DEA concludes that perampanel, including its salts, isomers, and salts of isomers, warrants control in schedule III of the CSA. 21 U.S.C. 812(b)(3).

Requirements for Handling Perampanel

Upon the effective date of this final rule, any person who handles perampanel is subject to the CSA's schedule III regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engagement of research, and conduct of instructional activities, of schedule III controlled substances including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) perampanel, or who desires to handle perampanel, 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 as of January 2, 2014. Any person who is currently engaged in any of the above activities and is not registered with the DEA must

submit an application for registration and may not continue their activities as of January 2, 2014 unless the DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Security. Perampanel is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93, pursuant to 21 U.S.C. 823, 821, 871(b) as of January 2, 2014.

Labeling and Packaging. All labels and labeling for commercial containers of perampanel must be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825, 958(e) as of January 2, 2014.

Inventory. Every DEA registrant who possesses any quantity of perampanel on the effective date of this final rule is required to take an inventory of all stocks of perampanel on hand as of January 2, 2014, pursuant to 21 U.S.C. 827, 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d). Any person who becomes registered with the DEA after January 2, 2014 is required to take an initial inventory of all controlled substances (including perampanel) on hand at the time of registration, pursuant to 21 U.S.C. 827, 958(e) and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b). After the initial inventory, every DEA registrant is required to take a biennial inventory of all controlled substances (including perampanel), on hand pursuant to 21 U.S.C. 827, 958(e) and in accordance with 21 CFR 1304.03, 1304.04 and 1304.11.

Records. All DEA registrants must keep records with respect to perampanel pursuant to 21 U.S.C. 827, 958(e) and in accordance with 21 CFR parts 1304, 1307, and 1312, as of January 2, 2014.

Prescriptions. All prescriptions for perampanel or prescriptions for products containing perampanel must comply with 21 U.S.C. 829 and must be issued in accordance with 21 CFR part 1306 as of January 2, 2014.

Importation and Exportation. All importation and exportation of perampanel must be done in accordance with 21 CFR part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958 as of January 2, 2014.

Criminal Liability. Any activity involving perampanel not authorized by, or in violation of, the CSA, occurring as of January 2, 2014 is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

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 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. It 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 Deputy Administrator, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), has reviewed this rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to place perampanel, including its salts, isomers, and salts of isomers, into schedule III of the CSA. No less restrictive measures (i.e., non-control or control in a lower schedule) enable the DEA to meet its statutory obligations under the CSA. In preparing this certification, the DEA has assessed economic impact by size category and has considered costs with respect to the various DEA registrant business activity classes.

Perampanel is a new molecular entity, approved by the FDA on October 22, 2012. It was approved in Europe in May 2012, and has been marketed in Europe since July 2012. According to publically available information reviewed by the DEA, perampanel is currently anticipated to enjoy patent protection for at least a decade before generic equivalents may be manufactured and marketed. Accordingly, the number of currently identifiable manufacturers, importers, and distributors for perampanel is extremely small. The publically available materials also specify the readily identifiable persons subject to direct regulation by this final rule. Based on guidelines utilized by the Small Business Administration (SBA), the perampanel manufacturer/distributor/importer was determined not to be a small entity. Once generic equivalents are developed and approved for manufacturing and marketing, there may be additional manufacturers, importers, and distributors of perampanel, but whether they may qualify as small entities cannot be determined at this time.

There are approximately 1.5 million controlled substance registrants, who represent approximately 381,000 entities. The DEA estimates that 371,000 (97 percent) of these businesses are considered ''small entities'' in accordance with the RFA and SBA standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. Due to the wide variety of unidentifiable and unquantifiable variables that could potentially influence the dispensing rates of new chemical entities, the DEA is unable to determine the number of small entities that might dispense (including administer and prescribe) perampanel (e.g., pharmacies and prescribers).

Despite the fact that the number of small businesses potentially impacted by this final rule could not be determined at this time, the DEA concludes that they would not experience a significant economic impact as a result of this rule. The DEA estimates all anticipated perampanel handlers to be DEA registrants and currently 98 percent of DEA registrants (most of which are small businesses) are authorized to handle schedule III controlled substances. Even if we assume that all of the DEA registrants were to dispense perampanel, (e.g., practitioners prescribe, administer, or dispense the substance, and pharmacies dispense the prescriptions), the costs that they would incur as a result of perampanel scheduling would be

minimal. Registrants that dispense (but not prescribe) would incur nominal additional security, inventory, recordkeeping, and labeling costs, as they have already established and implemented the required systems and processes to handle schedule III controlled substances. For example, pharmacies and institutional practitioners may disperse schedule II–V controlled substances throughout their stock of non-controlled substances in such a manner as to obstruct theft or diversion of the controlled substances. The inclusion of one additional substance to this system would result in little or no additional burden to such practitioners. In addition, because DEA-registered dispensers must label all schedule II–V controlled substances dispensed, the requirement to label all controlled substances containing perampanel would not impose a significant economic burden upon DEA-registered dispensers (as the infrastructure and materials for doing so would already be in place). Accordingly, compliance would not require significant manpower, capital investments, or recordkeeping burdens.

Registrants who only prescribe perampanel by oral or written prescription would not incur any additional security, inventory, recordkeeping, or labeling costs as a result of this rule, as they would not physically handle perampanel.

Because of these facts, this rule will not result in significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), on the basis of information contained in the ''Regulatory Flexibility Act'' section above, the DEA has determined and certifies pursuant to UMRA that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA of 1995.

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). This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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 rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; 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. However, pursuant to the CRA, the DEA has submitted a copy of this final rule 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, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. Amend § 1308.13 by redesignating paragraphs (c)(11) through (c)(14) as paragraphs (c)(12) through (c)(15) and adding new paragraph (c)(11) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(c) * * *

(11) Perampanel, and its salts, isomers, and salts of isomers	2261

* * * * *

Dated: November 25, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–28778 Filed 11–29–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[TD 9647]

RIN 1545–BL37

User Fees for Processing Installment Agreements and Offers in Compromise

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide user fees charged for processing installment agreements and offers in compromise. The final regulations affect taxpayers who wish to pay their federal tax liabilities through installment agreements and offers in compromise.

DATES: *Effective date:* These regulations are effective on December 2, 2013.

Applicability Date: These regulations apply to installment agreements entered into, restructured, or reinstated and offers in compromise processed on or after January 1, 2014.

FOR FURTHER INFORMATION CONTACT: Concerning cost methodology, Eva Williams, at (202) 803–9728; concerning the regulations, Girish Prasad, at (202) 317–5429 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

This document contains amendments to 26 CFR part 300. On August 30, 2013, a notice of proposed rulemaking (REG–144990–12) relating to the user fees charged for processing installment agreements and offers in compromise was published in the **Federal Register** (78 FR 53702). The charging of user fees for services provided by agencies is authorized by the Independent Offices Appropriations Act (IOAA), which is codified at 31 U.S.C. 9701. Under the IOAA and OMB Circular A–25, 58 FR 38142 (July 15, 1993) (the OMB Circular), the charges must be fair and must be based on the costs to the government, the value of the service to the recipient, the public policy or interest served, and other relevant facts. In general, the amount of a user fee should recover the cost of providing the service, unless the Office of Management and Budget (OMB) grants an exception under the OMB Circular.

The notice of proposed rulemaking proposed to increase the fee under § 300.1 for entering into an installment agreement from $105 to $120 and to increase the fee under § 300.2 for