

# Rules and Regulations

Federal Register

Vol. 76, No. 241

Thursday, December 15, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-354]

#### Schedules of Controlled Substances: Placement of Ezogabine Into Schedule V

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance ezogabine, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule V of the Controlled Substances Act (CSA). This action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

**DATES:** Effective date: December 15, 2011.

#### FOR FURTHER INFORMATION CONTACT:

Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

#### SUPPLEMENTARY INFORMATION:

##### Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended (hereinafter, “CSA”). The implementing regulations for these statutes are found in Title 21 of the Code of Federal Regulations (CFR), parts

1300 to 1321. 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 by statute 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 subsection (b) of section 812 of this title 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 DEA.

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 HHS, 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 for Health of the Department of Health and Human Services (HHS) and on an evaluation of all other relevant data by DEA. This action imposes the regulatory controls and criminal sanctions of Schedule V on the manufacture, distribution, dispensing, importation, and exportation of ezogabine and products containing ezogabine.

Pursuant to 21 CFR 1308.44(e), the Administrator of DEA may issue her final order “[I]f all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the hearing.” As no requests for a hearing were filed on this proposed scheduling action, all interested persons are deemed to have waived their opportunity for a hearing pursuant to 21 CFR 1308.44(d), and the Administrator may issue her final order without a hearing.

Ezogabine is a new drug with a novel mechanism of action for the treatment of partial onset seizures. Because ezogabine is a new drug with possible immediate medical application to a life-

threatening illness not always treatable with medications currently available and because it may not be prescribed in the United States until this final rulemaking action is in effect and the subsequent requirements that result from this final action are satisfied, the Administrator hereby finds that it is in the interest of public health to forego the 30 day period prior to this final rule taking effect. This will impose no hardship on any interested party and is responsive to comments intended to facilitate the availability of ezogabine as soon as possible for that population of people suffering from seizures that may benefit from treatment with ezogabine. Therefore, in accordance with this finding of conditions of public health and of good cause to waive the 30 day period and pursuant to 21 CFR 1308.45 and 5 U.S.C. 553(d)(3), this final rule is effective upon publication.

#### Background

Ezogabine, known chemically as N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester, is a new chemical substance with central nervous system depressant properties and is classified as a sedative-hypnotic. Pharmacological studies indicate that ezogabine primarily acts as a ligand at ion-gated channels in the brain to enhance potassium currents mediated by neuronal KCNQ (Kv7) channels. Additionally, ezogabine indirectly enhances the gamma-aminobutyric acid (GABA) mediated neurotransmission. On June 10, 2011, the Food and Drug Administration (FDA) approved a New Drug Application (NDA) for ezogabine as an adjunct treatment of partial onset seizures, to be marketed under the trade name Potiga®.<sup>1</sup>

#### Determination To Schedule Ezogabine

Pursuant to 21 U.S.C. 811(a), proceedings to add a drug or substance to those controlled under the CSA may be initiated by request of the Secretary of HHS. On January 12, 2011, HHS provided DEA with a scientific and medical evaluation document prepared by FDA entitled “Basis for the Recommendation for Control of Ezogabine in Schedule V of the Controlled Substances Act.” Pursuant to 21 U.S.C. 811(b), this document

<sup>1</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2011/022345Orig1s000TOC.cfm](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022345Orig1s000TOC.cfm); as of July 21, 2011.

contained an eight-factor analysis of the abuse potential of ezogabine as a new drug, along with HHS' recommendation to control ezogabine under Schedule V of the CSA. In response, DEA conducted an eight-factor analysis of ezogabine's abuse potential pursuant to 21 U.S.C. 811(c).

Following analysis, the Administrator of DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of Ezogabine into Schedule V" on October 21, 2011 (76 FR 65424), which proposed placement of ezogabine into Schedule V of the CSA. The proposed rule provided an opportunity for all interested persons to request a hearing or to submit comments on or before November 21, 2011.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in the scheduling decision. Please note that both the DEA and HHS analyses are available under "Supporting and Related Material" of the public docket for this rule at [www.regulations.gov](http://www.regulations.gov) under docket number DEA-354.

**1. The Drug's Actual or Relative Potential for Abuse:** Ezogabine is a new chemical substance that has not been marketed in the U.S. As such, there is no information available which details actual abuse of ezogabine. However, the legislative history of the CSA offers another methodology for assessing a drug or substance's potential for abuse:

The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.<sup>2</sup>

Ezogabine acts as a ligand at ion-gated channels in the brain, similar to the Schedule V substances pregabalin and lacosamide, and, like those drugs, ezogabine is indicated for the treatment of epileptic conditions in humans. There is strong evidence, described below, that ezogabine produces behavioral effects in humans and in animals that are similar to those produced by pregabalin and lacosamide.

Phase 1 clinical studies indicate that the rate of euphoria-related adverse events (AEs) resulting from administration of ezogabine was 6–9%.

<sup>2</sup>Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); 1970 U.S.C.C.A.N. 4566, 4601.

This is similar to the AE rates for administration of pregabalin (10%) and lacosamide (>7%), while Phase 2/3 clinical studies indicated similar AE rates between ezogabine (<1%) and lacosamide (<2%). Animal studies involving administration of ezogabine to animals produced a sedative behavioral profile similar to that produced from administration of pregabalin and lacosamide, including decreased locomotion, decreased muscle tone, and an increase in ataxia. Further, in abuse potential studies conducted with sedative-hypnotic abusers, ezogabine, pregabalin, and lacosamide, when compared to placebos, are similar in their ability to produce statistically significant increases in subjective responses including "Drug Liking," "Euphoria," "Overall Drug Liking," "Good Drug Effects," and "High."

Because of the similarities between ezogabine, pregabalin, and lacosamide, it is very likely that ezogabine will have an abuse potential similar to those Schedule V substances. Currently there is a lack of evidence regarding the diversion, illicit manufacturing or deliberate misuse of ezogabine due to its commercial unavailability in any country, but since ezogabine is not readily synthesized from available substances, any diversion would be from legitimate channels. The above referenced studies, which include demonstration of the significant euphoric effects produced by ezogabine in humans, predict that there will be significant use of ezogabine contrary to or without medical advice.

**2. Scientific Evidence of the Drug's Pharmacological Effects, If Known:** Ezogabine acts to enhance potassium currents mediated by neuronal KCNQ (Kv7) channels with a secondary action through the augmentation of GABA-mediated neurotransmission without direct GABA receptor stimulation. In individuals with histories of recreational sedative-hypnotic abuse, ezogabine (300 and 600 mg orally) produced increased ratings on the primary positive subjective scales [VAS-Drug-liking, VAS-Overall Drug Likning, ARCI-MBG (Euphoria), VAS-Take Drug Again] for peak responses (Emax for the first eight hours after drug administration) that were significantly different from the placebo. This effect is similar to that produced by alprazolam (1.5 and 3.0 mg orally; Schedule IV). On secondary positive subjective scales [VAS-High, VAS-Good Effects, ARCI-Amphetamine (Activation)] for peak responses, both ezogabine and alprazolam produced significant increases compared to the placebo, while there were no differences between

ezogabine and alprazolam on those measures.

In human abuse potential studies, ezogabine (300 and 600 mg), upon oral administration, increased ratings on negative and sedating subjective measures [VAS-Bad Effects, ARCI-LSD (dysphoria) and ARCI-PCAG (sedation)] compared to the placebo, but these increases were lower than those produced by 1.5 and 3.0 mg alprazolam. These data for ezogabine are similar to those produced by lacosamide. A 900 mg dose of ezogabine produced VAS-Drug Liking and VAS-Good Effects that were higher than those produced by the two lower doses of ezogabine and either dose of alprazolam. However, the changes in VAS-Bad Effects and ARCI-LSD (dysphoria) following 900 mg ezogabine were less than or similar to those produced by lower doses of ezogabine and either dose of alprazolam. The adverse events following 900 mg ezogabine are similar to those described in the NDA file for the human abuse potential study conducted with lacosamide. These included euphoria, somnolence, visual disturbances, and altered auditory perception.

In human abuse potential studies, ezogabine, similar to pregabalin and lacosamide, also produced ratings on each of the positive subjective responses that were statistically similar to those produced by Schedule IV benzodiazepines (alprazolam or diazepam). Although this appears to suggest that these drugs have an abuse potential similar to that of Schedule IV substances, the other data from human abuse potential studies, the adverse effect profile data from safety and efficacy studies, and the data from the preclinical animal behavioral studies demonstrate that ezogabine has abuse potential less than that of Schedule IV drugs but similar to that of Schedule V drugs.

**3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance:** The chemical name of ezogabine is N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester. It is an achiral molecule with a molecular formula of C<sub>16</sub>H<sub>18</sub>FN<sub>3</sub>O<sub>2</sub> and a molecular weight of 303.3 g/mol. Ezogabine is a non-hygroscopic white to slightly colored powder with a melting point of 140–143 °C. It is soluble in 0.9% saline, methanol, chloroform, but only sparingly soluble in ethanol and 0.1N HCl.

Ezogabine in humans has a T<sub>max</sub> (time required for ezogabine to reach maximum plasma concentration) ranging from 1–4 hours following both

acute and multiple dosing, and, without the involvement of cytochrome P450, undergoes an extensive and almost exclusively phase 2 metabolic biotransformation. Ezogabine is predominantly metabolized by N-glucuronidation, resulting in the formation of two distinct N-glucuronides of the unchanged parent drug and to a lesser extent by N-acetylation to form N-acetyl-retigabine, the major bioactive metabolite of ezogabine. The half-life of both ezogabine and N-acetyl-retigabine is approximately eight hours and the  $C_{max}$  (maximum plasma concentration) of both components is dose proportional after both acute and multiple dosing, suggesting a lack of accumulation with repeated administration.

**4. Its History and Current Pattern of Abuse:** As stated in the summary of Factor 1, information on ezogabine's history and current pattern of abuse is unavailable as it has not been marketed in any country. As such, evaluation of abuse potential for ezogabine derives from positive indicators in clinical studies which are believed to be predictive of drug abuse and which are discussed in Factors 1 and 2 above.

**5. The Scope, Duration, and Significance of Abuse:** Because ezogabine has not yet been marketed, information on the scope, duration, and significance of abuse of ezogabine is unavailable. However, epidemiological data on pregabalin, a Schedule V drug with an abuse potential similar to that of ezogabine, is available from the Drug Abuse Warning Network (DAWN) database.

The "abuse frequency ratio," calculated as the ratio of nonmedical use related annual emergency department visits (as reported in DAWN) to the total number of annual prescriptions for pregabalin is less than that for the Schedule IV drug, alprazolam. Further, because ezogabine has abuse-related human and animal data in its NDA file similar to data generated for pregabalin, ezogabine is likely to have an abuse potential similar to pregabalin. The "abuse frequency ratios" for pregabalin range from 29 to 47, while those for alprazolam are approximately three to six times higher, ranging from 160 to 235. Thus, pregabalin was placed into Schedule V based both on abuse-related human and animal data submitted in its NDA and by epidemiological data which justified placement relative to drugs in Schedule IV. Given that ezogabine has abuse-related human and animal data in its NDA file similar to the data generated by pregabalin, it is likely that ezogabine

will have an abuse potential similar to this Schedule V drug.

**6. What, if any, Risk There is to the Public Health:** The data indicates that ezogabine may present a serious safety risk to the public health, and the predicted level of risk is similar to that observed with pregabalin and lacosamide but less than that produced by Schedule IV benzodiazepines. In Phase 1 clinical safety studies, the overall adverse event profile following ezogabine administration was similar to those from pregabalin and lacosamide and includes not only euphoria, but also somnolence, and feeling or thinking abnormally. Further, the human abuse potential study showed that the majority of subjects receiving the 900 mg dose of ezogabine experienced multiple adverse events such as euphoria, somnolence, visual disturbance, amnesia, hypoesthesia, paranoia, fear, confusion and hallucination. Although the 900 mg dose is three times greater than the recommended therapeutic dose, individuals who abuse drugs typically do so at supra-therapeutic doses.

**7. Its Psychic or Physiological Dependence Liability:** Ezogabine may produce limited psychic or physiological dependence liability following extended administration. Since there are no studies detailing abrupt discontinuation of ezogabine, there are minimal adequate data to evaluate the ability of ezogabine to induce withdrawal symptoms that are indicative of physical dependence. Many of the adverse events reported from the discontinuation of ezogabine were also reported prior to its discontinuation, including dizziness, somnolence, and a state of confusion. By comparison, abrupt or rapid discontinuation of pregabalin in human studies resulted in patient-reported symptoms of nausea, headache or diarrhea, which are suggestive of physical dependence, while abrupt termination of lacosamide produced no signs or symptoms of withdrawal in diabetic neuropathic pain patients.

Unlike ezogabine and pregabalin, the withdrawal syndrome following discontinuation of Schedule IV substances such as alprazolam can range from mild dysphoria and insomnia to a major syndrome including abdominal pain, muscle cramps, vomiting, sweating, tremors and convulsions. These are similar in character to those associated with other sedative-hypnotics.

The study of ezogabine abuse potential in humans with histories of recreational abuse of sedative-hypnotics found that ezogabine produces euphoria (18–33%) in these individuals.

Additionally, ezogabine produced euphoria (8.5%) in Phase 1 studies in healthy individuals. These euphoria-related adverse events following administration of ezogabine are suggestive of its ability to produce psychic dependence, and the adverse events appear to be less severe and occur less frequently than Schedule IV drugs (diazepam and alprazolam) and are more similar to those of Schedule V drugs, pregabalin and lacosamide.

**8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:** Ezogabine is not an immediate precursor of any controlled substance.

#### Requests for a Hearing and Comments

DEA received no requests for a hearing on this scheduling action. DEA received two comments on the NPRM to schedule ezogabine.

**Comment:** The first comment requested that ezogabine be placed into Schedule IV of the CSA instead of Schedule V as proposed. While the commenter stated that ezogabine may help those who have not had success with current epilepsy treatments, the commenter believed that ezogabine's new mechanism of action, including its effect on the central nervous system as an anticonvulsant and the potential side effects of the drug therein, warrant closer scrutiny and supervision under Schedule IV.

**DEA Response:** DEA disagrees. That ezogabine has an effect on the central nervous system is alone not enough to merit its inclusion into Schedule IV of the CSA, nor is the possibility that persons to whom ezogabine is prescribed would need to monitor their medications closely. Instead, as detailed in the HHS and DEA analyses and the HHS recommendation, studies indicate that the abuse potential and likely effects of ezogabine are similar to those of the Schedule V drugs pregabalin and lacosamide, and, therefore, merit ezogabine's inclusion into Schedule V of the CSA.

**Comment:** The second comment stated that because epilepsy is a serious and potentially life-threatening illness that may not be adequately treated with currently available medicines, conditions of public health necessitate an early effective date for the final rule pursuant to 21 CFR 1308.45. As such, the commenter requested an effective date for the rule concurrent with its publication in the **Federal Register**.

**DEA Response:** As stated under "Legal Authority," DEA agrees that this rule should become effective upon publication. Ezogabine, unlike the currently available anticonvulsant

medications, may act as an anticonvulsant through a novel mechanism of action. Because some patients with epilepsy do not achieve satisfactory seizure control from treatments currently in use, the availability of ezogabine becomes an important and potentially life-saving option for such patients. Thus, for public health reasons pursuant to 21 CFR 1308.45 and based on finding good cause pursuant to 5 U.S.C. 553(d)(3) as outlined, this final rule is effective upon publication in the **Federal Register**.

#### Scheduling Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of ezogabine. As such, DEA will schedule ezogabine 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 to place 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 HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(5), finds that:

(1) Ezogabine has a low potential for abuse relative to the drugs or other substances in Schedule IV. The overall abuse potential of ezogabine is comparable to the Schedule V substances such as pregabalin and lacosamide;

(2) Ezogabine has a currently accepted medical use in treatment in the United States. Ezogabine was approved for marketing by FDA as an adjunct treatment of partial onset seizures; and

(3) Abuse of ezogabine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

Based on these findings, the Administrator of DEA concludes that ezogabine, including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in Schedule V of the CSA (21 U.S.C. 812(b)(5)).

#### Requirements for Handling Ezogabine

Upon the effective date of this final rule, ezogabine is subject to the CSA

and the Controlled Substances Import and Export Act (CSIEA) regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule V controlled substance, including the following:

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with ezogabine, or who desires to manufacture, distribute, dispense, import, export, engage in research or conduct instructional activities with ezogabine, must be registered to conduct such activities pursuant to 21 U.S.C. 822 and in accordance with 21 CFR Part 1301.

**Security.** Ezogabine is subject to Schedules III–V security requirements and must be manufactured, distributed, and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

**Labeling and Packaging.** All labels and labeling for commercial containers of ezogabine which are distributed on or after the effective date of this final rule must be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825.

**Inventory.** Every registrant required to keep records and who possesses any quantity of ezogabine must keep an inventory of all stocks of ezogabine on hand pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Every registrant who desires registration in Schedule V for ezogabine must conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants must keep records pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, 1304.06, 1304.21, 1304.22, and 1304.23.

**Prescriptions.** Ezogabine or products containing ezogabine must be distributed or dispensed pursuant to 21 U.S.C. 829 and in accordance with 21 CFR 1306.03–1306.06, 1306.08, 1306.21, and 1306.23–1306.27.

**Importation and Exportation.** All importation and exportation of ezogabine must be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958.

**Criminal Liability.** Any activity with ezogabine not authorized by, or in violation of, Subchapter I Part D and Subchapter II of the CSA or the CSIEA occurring on or after the effective date of this final rule is unlawful.

#### 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 done “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 criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget 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 ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

##### *Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law or impose enforcement responsibilities on any state or 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.

##### *Executive Order 13175*

This rule will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

##### *Paperwork Reduction Act of 1995*

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

##### *Congressional Review Act*

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

##### *List of Subjects in 21 CFR Part 1308*

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

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

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

- 1. The authority citation for 21 CFR Part 1308 continues to read as follows:

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

- 2. Section 1308.15 is amended by redesignating paragraphs (e)(1) and (2) as paragraphs (e)(2) and (3), and adding a new paragraph (e)(1) to read as follows:

### § 1308.15 Schedule V.

\* \* \* \* \*

(e) \* \* \*  
 (1) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]—2779

\* \* \* \* \*

Dated: December 8, 2011.

**Michele M. Leonhart,**

*Administrator.*

[FR Doc. 2011-32172 Filed 12-14-11; 8:45 am]

BILLING CODE 4410-09-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2011-0893; Airspace Docket No. 11-ANM-18]

#### Modification of Class E Airspace; The Dalles, OR

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action modifies Class E airspace at The Dalles, OR. Controlled airspace is necessary to accommodate aircraft using Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Columbia Gorge Regional/The Dalles Municipal Airport. This action also changes the airport name. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport.

**DATES:** Effective date, 0901 UTC, April 5, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

**FOR FURTHER INFORMATION CONTACT:**  
 Eldon Taylor, Federal Aviation

Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4537.

#### SUPPLEMENTARY INFORMATION:

##### History

On October 12, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to modify controlled airspace at The Dalles, OR (76 FR 63235). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

##### The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace extending upward from 700 feet above the surface, at Columbia Gorge Regional/The Dalles Municipal Airport, to accommodate IFR aircraft executing RNAV (GPS) standard instrument approach procedures at the airport. This also notes the airport's name change from The Dalles Municipal Airport to Columbia Gorge Regional/The Dalles Municipal Airport. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This

rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it creates additional controlled airspace at Columbia Gorge Regional/The Dalles Municipal Airport, The Dalles, OR.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

- 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

#### § 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011 is amended as follows:

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

\* \* \* \* \*

#### ANM OR E5 The Dalles, OR [Modified]

Columbia Gorge Regional/The Dalles Municipal Airport, OR  
 (Lat. 45°37'07" N., long. 121°10'02" W.)  
 Klickitat VOR/DME  
 (Lat. 45°42'49" N., long. 121°06'03" W.)

That airspace extending upward from 700 feet above the surface within a 12.9-mile radius of Columbia Gorge Regional/The Dalles Municipal Airport; that airspace extending upward from 1,200 feet above the surface within a 20.1-mile radius of the VOR/DME extending clockwise from the 088° radial to the 272° radial.

Issued in Seattle, Washington, on December 6, 2011.

**Johanna Forkner,**

*Acting Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2011-32043 Filed 12-14-11; 8:45 am]

BILLING CODE 4910-13-P