concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave., SW., Washington, DC 20591, *Attn:* Information Collection Clearance Officer, AES–200.

Related Information

(h) Refer to MCAI EASA AD No.: 2011–0146, dated August 3, 2011; Schempp-Hirth Flugzeugbau GmbH Technical Note No. 863–14, dated July 18, 2006; and Schempp-Hirth Flugzeugbau GmbH Technical Note No. 864–20 Revision 1, dated July 27, 2011, for related information. For service information related to this AD, contact Schempp-Hirth Flugzeugbau GmbH, Krebenstrasse 25, D–73230 Kirchheim/Teck, Germany; *phone:* +49 7021 7298–0; fax +49 7021 7298–199; *Internet: http://www.schempp-hirth.com; e-mail: info@schempp-hirth.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on October 17, 2011.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–27267 Filed 10–20–11; 8:45 am]

BILLING CODE 4910–13–P

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: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing 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 proposed 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: DEA will permit interested persons to file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted and written comments must be postmarked on or before November 21, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' [1] may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notices of appearance, and waivers of participation must be received on or before November 21, 2011.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–354'' on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental information to this proposed rule are also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/OD, 8701 Morrissette Drive, Springfield, VA 22152. All requests for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, VA 22152.

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:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information'' paragraph.

Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557) and 21 CFR 1308.41. Pursuant to 21 CFR 1308.44(a)–(c), requests for hearing, notices of appearance, and waivers of participation may be submitted only by interested persons, defined as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).'' Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b) and 1316.47 or 1316.48, as applicable. A request or notice should state, with particularity, the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c), including a written statement regarding the interested

[1] 21 CFR 1300.01.

person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a), the purpose and subject matter of the hearing is restricted to ''(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] 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 * * *'' Requests for hearing, notices of appearance at the hearing, and waivers of participation in the hearing should be submitted to DEA using the address information provided above.

Legal Authority

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 are 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 proposed 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. If finalized, this action would impose the regulatory controls and criminal sanctions of Schedule V on the manufacture, distribution, dispensing, importation, and exportation of ezogabine and products containing ezogabine.

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.®[2]

Proposed 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 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). 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 in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *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. or in any other country. 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.[3]

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%. 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:*

[2] *http://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022345Orig1s000TOC.cfm*; as of July 21, 2011.

[3] 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.

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 Liking, 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 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 $C_{16}H_{18}FN_3O_2$ and a molecular weight of 303.3 g/mol. Ezogabine is a non-hygroscopic white to slightly colored powder with a melting point of 140–143ºC. 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_{max} (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 been marketed in any country, 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 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 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, hypo-aesthesia, 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.

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 hereby proposes to schedule ezogabine as a controlled substance under the CSA.

Proposed 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

If this rule is finalized as proposed, ezogabine would be 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, would need to be registered to conduct such activities pursuant to 21 U.S.C. 822 and in accordance with 21 CFR part 1301.

Security. Ezogabine would be subject to Schedules III–V security requirements and would need to 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 finalization of this rule would need to 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 would be required to 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 would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to 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 would be required to 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 would need to 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 finalization of this proposed rule would be unlawful.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed 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 proposed 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 proposed 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.

Executive Order 13175

This proposed 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.

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 proposed to be amended to read 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—2779

* * * * *

Dated: October 14, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–27253 Filed 10–20–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 524

[BOP–1155–P]

RIN 1120–AB55

Classification and Program Review

AGENCY: Bureau of Prisons, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Bureau of Prisons (Bureau) proposes to revise its regulations on classification and program review to ensure that classification and program review procedures adequately address inmate needs. This proposed rule also adds a new type of review, the ''progress review.'' A progress review will be an abbreviated program review meant to focus on an inmate's programming activities. This shortened version of the more thorough program review will facilitate more efficiently-used staff and inmate time, in that it will primarily focus on any new or changed aspects of an inmate's initial classification and participation in recommended programs. Inmates who have 36 months or more until their projected release date will receive alternating program and progress reviews at least once every 180 calendar days, a practice that will allow the Bureau to more efficiently utilize staff time and resources. The process will also allow staff to devote more time and resources to the reviews of inmates who are closer to their release dates, enabling the Bureau to better fulfill its mission to prepare inmates for eventual release into communities within the United States.

DATES: Comments due by December 20, 2011.

ADDRESSES: Comments should be submitted to the Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. You may also comment via the Internet to BOP at *BOPRULES@BOP.GOV* or by using the *http://www.regulations.gov* comment form for this regulation. When submitting comments electronically you must include the BOP Docket No. in the subject box.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and are made available for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, *etc.*) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on *http://www.regulations.gov.*

Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. Confidential business information identified and located as set forth above will not be placed in the public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information Contact'' paragraph.

Proposed Rule

In this document, we propose to revise the regulations which set forth the classification and program review rules and to add a new level of review: progress reviews.

Section 524.10 Purpose

In this proposed section, we explain that the purpose of this subpart is to explain the Bureau's process for classifying newly committed inmates, conducting program reviews, and conducting progress reviews. We have only revised the introductory paragraph of this section, to add the concept of progress reviews (which will be explained below). The three types of reviews listed here will be conducted for all inmates except: (1) Pretrial inmates, who are covered in 28 CFR part 551; and (2) inmates committed for study and observation.

Pretrial inmate reviews are not described in this subpart because they are specifically covered in 28 CFR 551.107. According to that regulation, pretrial inmates are scheduled for an initial review by the unit team within 21 calendar days of the inmate's arrival at the institution, and later reviews are conducted at least once every 90 days.

Inmates committed for study and observation do not receive the reviews described because they do not receive program or work assignments while in this status. Such inmates are typically committed to the Bureau to determine competency to stand trial or for other mental health or medical assessments, and are inappropriate for assignment to work or other Bureau programs.