detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Eurocopter Deutschland GmbH: Docket No. FAA–2011–1285; Directorate Identifier 2010–SW–073–AD.

(a) Applicability

This AD applies to Model BO–105A, BO–105C, BO–105LS A–1, BO–105LS A–3, and BO–105S helicopters, with a main rotor blade, part number 105–15103, 105–15141, 105–15141V001, 105–15143, 105–15150, 105–15150V001, 105–15152, 105–81013, 105–87214, 1120–15101, or 1120–15103; where the main rotor blade erosion protective shell (abrasion strip) was replaced between September 1, 2006 and March 31, 2010, inclusive; certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as debonding of a main rotor blade erosion protective shell (abrasion strip). This condition could result in loss of the abrasion strip and an unbalanced main rotor, high vibration, damage to the tail boom or tail rotor, and loss of control of the helicopter.

(c) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(d) Required Actions

(1) Within 50 hours time-in-service, inspect the main rotor blade for debonding of the erosion protective shell by tap testing the abrasion strip of the leading edge of each main rotor blade.

(2) If the abrasion strip is debonding in any area, before further flight, replace the main rotor blade.

(e) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Jim Grigg, Manager, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5110; email *jim.grigg@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(f) Additional Information

(1) Eurocopter Emergency Alert Service Bulletin No. ASB BO105–10–124, Revision 1, dated October 18, 2010, and No. ASB–BO105LS–10–12, Revision 1, dated October 20, 2010, which are not incorporated by reference, contain additional information about the subject of this AD. For this service information, contact American Eurocopter Corporation, 2701 N. Forum Drive, Grand Prairie, Texas 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.eurocopter.com/techpub.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(2) The subject of this AD is addressed in European Aviation Safety Agency Emergency AD No. 2010–0216–E, dated October 21, 2010 (corrected October 29, 2010).

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6210, Main Rotor Blades.

Issued in Fort Worth, Texas, on December 12, 2012.

S. Frances Cox,

Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2012–30588 Filed 12–18–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–369]

Schedules of Controlled Substances: Placement of Lorcaserin Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing the substance lorcaserin, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule IV of the Controlled Substances Act (CSA). 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 IV on the manufacture, distribution, dispensing, importation, exportation, and possession of lorcaserin and products containing lorcaserin.

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 January 18, 2013. 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 or waiver of participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45. Requests for hearing and waivers of participation must be received on or before January 18, 2013.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–369'' 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 *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 and waivers of participation must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 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 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 Contact'' paragraph, above.

Requests for Hearing 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) and (c), requests for a hearing 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).'' [2] Requests for a hearing must conform to the requirements of 21 CFR 1308.44(a) and 1316.47. A request 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 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 and waivers of participation in the hearing should be submitted to DEA using the address information provided above. DEA may grant a hearing only ''for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable'' pursuant to 21 U.S.C. 811(a).

Legal Authority

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 (CSA) and the Controlled Substances Import Export Act (CSIEA) (21 U.S.C. 801–971), as amended (hereinafter, ''CSA'').

Under the CSA, controlled substances are classified in one of five schedules based upon their potential for abuse, their currently accepted medical use, safety and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances are found at 21 U.S.C. 812(c). 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.

Background

Lorcaserin ((*R*)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzepine hydrochloride hemihydrate) is a new chemical entity which has central nervous system hallucinogenic properties. Lorcaserin is a serotonin receptor agonist, at the $5HT_{2C}$ and $5HT_{2A}$ receptor subtypes. Lorcaserin was approved by the Food and Drug Administration (FDA) on June 27, 2012, as an addition to a reduced-calorie diet and exercise, for chronic weight

[1] 21 CFR 1300.01.

[2] 21 CFR 1300.01.

management and it will be marketed under the trade name BELVIQ®.

Proposed Determination To Schedule Lorcaserin

Pursuant to the CSA, 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 June 25, 2012, HHS provided DEA with a scientific and medical evaluation document prepared by FDA entitled ''Basis for the Recommendation for Control of Lorcaserin in Schedule IV of the Controlled Substances Act.'' Pursuant to 21 U.S.C. 811(b), (c), and (f), this document contained an eight-factor analysis of the abuse potential of lorcaserin as a new drug, along with HHS' recommendation to control lorcaserin under Schedule IV of the CSA.

In response, DEA conducted an eight-factor analysis of abuse potential of lorcaserin pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as considered by HHS and DEA. Please note that both the DEA and HHS analyses are available in whole in the ''Supporting and Related Material'' of the public docket for this rule at *www.regulations.gov* under docket number DEA–369. Full analysis of and citations to the information referenced in the summary may be found in the supporting material.

1. *The Drug's Actual or Relative Potential for Abuse:* Lorcaserin 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 lorcaserin. 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]

According to HHS, lorcaserin is an agonist at the serotonin receptor subtypes 5–HT_{2C} and 5–HT_{2A}. Lorcaserin is indicated as an addition to a reduced-calorie diet and exercise, for chronic weight management. There is evidence, described below, that lorcaserin produces subjective effects in humans and in animals that are similar to those produced by zolpidem (Schedule IV) and ketamine (Schedule III)

HHS described a human abuse potential study in recreational drug abusers of psychedelic drugs and CNS depressants, in which lorcaserin and the comparator drugs zolpidem (Schedule IV) and ketamine (Schedule III) produced significant increases on positive subjective measures (visual analog scales (VAS)) for ''high'' and ''good drug effects as well as an increase on the VAS for ''hallucinations.'' Lorcaserin, as well as zolpidem and ketamine, significantly increased reports of ''sedation'' on the subjective scale of the Addiction Research Center Inventory (ARCI), compared to placebo. HHS summarized that these subjective response data suggest that lorcaserin produces subjective effects similar to those produced by zolpidem and ketamine. According to HHS, 20–60 mg of lorcaserin produced a high rate of euphoria in 6–19% of the subjects in a human abuse potential study. The incidence of euphoria following lorcaserin administration in the human abuse potential study is similar to that reported following zolpidem (Schedule IV) administration (13–16%) and lower than that following ketamine (Schedule III) administration (50%).

According to HHS, lorcaserin is not available or marketed in any country. Thus there is no evidence of lorcaserin diversion, illicit manufacturing, or deliberate ingestion. Because lorcaserin has been shown to produce euphoria in humans, it is anticipated that there will be significant use contrary to or without medical advice. Lorcaserin is not readily synthesized from available substances, and thus its diversion will be likely from the legitimate channels.

2. *Scientific Evidence of the Drug's Pharmacological Effects, If Known:* HHS stated that lorcaserin is a 5–HT_{2C} and 5–HT_{2A} serotonin receptor agonist. DEA further notes that it has been shown that lorcaserin through activation of 5–HT_{2C} receptors causes inositol phosphate accumulation with an EC_{50} of 9 nM. Lorcaserin also activated the 5–HT_{2A} and 5–HT_{2B} receptors, with EC_{50}s of 168 nM and 943 nM, respectively.

HHS stated that acutely, lorcaserin decreases locomotor activity in rats. Tolerance does develop to this effect, because after 21 days, lorcaserin does not affect the locomotor activity of the rats. DEA further notes that a study showed that food intake in rats was reduced after a single administration of lorcaserin. The doses administered were 3, 6, 12, and 24 mg/kg. Lorcaserin decreased the cumulative food intake at 2, 4, 6, and 22 hours. The ED_{50} for food intake inhibition was 18 mg/kg.

According to HHS' review, a drug discrimination study conducted in 2,5-dimethoxy-4-methylamphetamine (DOM)-trained rats showed that lorcaserin (0.1–10 mg/kg) produced full generalization (≥ 80%) to the DOM cue in 7 of 9 rats. DOM is a Schedule I hallucinogen and a 5-HT_{2A} and 5-HT_{2C} receptor agonist. These data suggest that lorcaserin in doses 0.1 to 10 mg/kg produces discriminative stimulus responses similar to DOM, a hallucinogen.

As described by HHS in a human abuse potential study with individuals with a history of abusing drugs, lorcaserin was evaluated for its abuse potential; it was compared to ketamine (Schedule III NMDA antagonist), zolpidem (Schedule IV GABA agonist), and a placebo. In clinical trials, lorcaserin, similar to ketamine and zolpidem, produced euphoric and hallucinogenic adverse events (AEs).

3. *The State of the Current Scientific Knowledge Regarding the Drug or Other Substance:* HHS states that lorcaserin ((*R*)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzepine hydrochloride hemihydrate) is water-soluble. The molecular formula is $C_{11}H_{14}ClN$ and its molecular weight is 241.6 g/mol, the CAS number is 616202–92–7.

According to HHS, in humans, lorcaserin is rapidly absorbed from the gastrointestinal tract after oral administration, the t_{max} (time to reach maximum plasma concentration) is ≤ 2 hours and its half-life in plasma is about 11 hours. DEA further notes that after a single oral administration of 10 mg/kg lorcaserin to rats, the absorption from the gastrointestinal tract was rapid, resulting in a mean maximum plasma concentration (C_{max}) of 0.76 μg/ml at 0.25 hour. The time from oral administration to brain maximal exposure was 1 hour.

According to HHS, the major circulating metabolite of lorcaserin is lorcaserin sulfamate (M1). Lorcaserin is metabolized by the liver and excreted by the kidney. M1 is considered inactive and it does not bind significantly to monoamine transporters. DEA further notes that the major metabolite in the urine is N-carbamoyl glucuronide (M5).

4. *Its History and Current Pattern of Abuse:* History and current pattern of abuse of lorcaserin is not available since it has not been marketed in any country. As stated in HHS' review, lorcaserin produced positive subjective effects in a human abuse potential study that are

[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.

similar to those produced by zolpidem (Schedule IV) and ketamine (Schedule III). HHS states that the positive subjective effects reported from supratherapeutic doses of lorcaserin administration, are predictive of its potential for abuse.

5. *The Scope, Duration, and Significance of Abuse:* According to the HHS review, the information on lorcaserin's scope, duration and significance of abuse is not available since it has not been marketed in any country. Thus, the evaluation of the significance of abuse of lorcaserin derives from positive indicators in pre-market clinical trials which are believed to be predictive of drug abuse. Based on the AEs reported in the clinical efficacy studies and the data from a human abuse potential lorcaserin study, HHS concluded that the scope and significance of the abuse potential of lorcaserin is similar to Schedule IV substances. HHS states that marketing lorcaserin as a Schedule IV substance will decrease its abuse, as opposed to marketing it as an uncontrolled or Schedule V substance.

6. *What, if any, Risk There is to the Public Health:* According to HHS, the abuse potential of lorcaserin presents a risk to the public health. HHS states that lorcaserin produces a number of AEs that are commonly seen with other Schedule IV substances that are abused. Some of these AEs include feeling jittery, psychomotor hyperactivity, paresthesia, abnormal dreams, and state of confusion. Headache, nausea, and dizziness were the most commonly reported AEs in lorcaserin clinical studies. In a human abuse potential study, 20–60 mg lorcaserin produced a high incidence of the AE euphoria in 6–19% of the subjects. According to HHS, because lorcaserin binds to 5-HT_2 receptors and generalizes to 5-HT_2 agonists in drug discrimination studies in rats, it is expected to have a hallucinogenic profile. DEA further notes that in the human abuse potential study conducted by Shram and colleagues (2011), supratherapeutic doses of lorcaserin were associated with significantly higher peak scores on the ''Detached'' (40 and 60 mg), ''Hallucinations'' (40 mg), and ''Spaced Out'' (40 and 60 mg) visual analog scales.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS' review, there were two clinical studies conducted to determine the ability of lorcaserin to induce physical dependence. The patients in these studies were obese and lorcaserin was administered for 4 and 12 weeks prior to drug discontinuation. Upon lorcaserin discontinuation, there were no signs of changes in mood, food interest, or body weight. Discontinuation of lorcaserin administration to animals also did not produce typical withdrawal symptoms. However, according to HHS, the ability of lorcaserin to produce hallucinations, euphoria, and positive subjective responses at supratherapeutic doses is suggestive of its potential to produce psychic dependence.

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

Conclusion: Based on consideration of the scientific and medical evaluation conducted by HHS and its recommendation, and after considering its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of lorcaserin. As such, DEA hereby proposes to schedule lorcaserin 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 in placing a drug or other substance in any 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), finds that:

(1) Lorcaserin has a low potential for abuse relative to the drugs or other substances in Schedule III. The overall abuse potential of lorcaserin is comparable to the Schedule IV substances;

(2) Lorcaserin has a currently accepted medical use in treatment in the United States. Lorcaserin was approved for marketing by FDA as an addition to a reduced-calorie diet and exercise, for chronic weight management; and

(3) Abuse of lorcaserin may lead to limited psychological dependence relative to the drugs or other substances in Schedule III. This finding is based on the ability of lorcaserin to produce positive subjective effects at supratherapeutic doses.

Based on these findings, the Administrator of DEA concludes that lorcaserin, 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 IV of the CSA (21 U.S.C. 812(b)(4)).

Requirements for Handling Lorcaserin

If this rule is finalized as proposed, lorcaserin would be subject to CSA regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with lorcaserin, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lorcaserin, 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. Lorcaserin 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 lorcaserin 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 lorcaserin would be required to keep an inventory of all stocks of lorcaserin 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 IV for lorcaserin 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, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for lorcaserin or prescriptions for products containing lorcaserin would be required to be issued as a controlled substance pursuant to 21 U.S.C. 829 and in accordance with 21 CFR 1306, including but not limited to 21 CFR 1306.03–1306.06, 1306.08, 1306.09, and 1306.21–1306.27.

Importation and Exportation. All importation and exportation of lorcaserin 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 lorcaserin not authorized by, or in violation of, Subchapter I Part D and Subchapter II of the CSA 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. 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Lorcaserin products, as recently approved by the FDA, will be used as an adjunct treatment of partial onset seizure. Handlers of lorcaserin will also handle other controlled substances used as anti-seizure agents, which are already subject to the regulatory requirements of the CSA.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act 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.

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 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

2. Section 1308.14 is amended by redesignating paragraphs (e) and (f) as paragraphs (f) and (g) and adding a new paragraph (e) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(e) *Lorcaserin.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Lorcaserin 1625

* * * * *

Dated: December 13, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012–30531 Filed 12–18–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–1013]

RIN 1625–AA00

Safety Zone; Woldenburg Park, Mississippi River, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Captain of the Port New Orleans, under the authority of the Ports and Waterways Safety Act, intends to establish a temporary safety zone on the Mississippi River in the vicinity of Woldenburg Park, mile marker 94 to mile marker 96, extending out 300 feet from the East Bank of the Mississippi River during Super Bowl 2013 celebratory events. The Super Bowl is a large scale event that poses many public safety concerns due to the number of people that will attend. This safety zone would be established to protect the public from the hazards created by congested river traffic. This rule would be effective from 6:00 a.m. on January 29, 2013 through 6:00 a.m. on February 4, 2013. The zone will be enforced between the hours of 8:00 a.m. and 10:00 p.m. on each day of the effective period described above.

DATES: Comments and related material must be received by the Coast Guard on or before December 30, 2012.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LCDR Kenneth Blair, Sector New Orleans, U.S. Coast Guard; telephone (504) 365–2392, email