Rules and Regulations

Federal Register
Vol. 78, No. 89
Wednesday, May 8, 2013

FARM CREDIT ADMINISTRATION

12 CFR Part 615

RIN 3052–AC54

Funding and Fiscal Affairs, Loan Policies and Operations, and Funding Operations; Liquidity and Funding; Correction

AGENCY: Farm Credit Administration.

ACTION: Final rule; correction.

SUMMARY: The Farm Credit Administration (FCA) published a final rule in the **Federal Register** on April 18, 2013 to strengthen liquidity risk management at Farm Credit System (System) banks, improve the quality of assets in their liquidity reserves, and bolster the ability of System banks to fund their obligations and continue operations during times of economic, financial, or market adversity. This document corrects that rule by replacing a term that was inadvertently used.

DATES: *Effective Date:* This regulation will be effective 30 days after publication in the **Federal Register** during which either or both Houses of Congress are in session. We will publish a notice of the effective date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: David Lewandrowski, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA, (703) 883–4498, TTY (703) 883–4056; or Richard A. Katz, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TTY (703) 883–4056.

SUPPLEMENTARY INFORMATION: The FCA published a document in the **Federal Register** on April 18, 2013, (78 FR 23438) amending part 615. In FR Doc. 2013–09166, make the following corrections on two separate pages.

■ 1. Remove the term ''book'' and add in its place, the term ''market'' on page 23453, in the first column, line 18.

§ 615.5134 [Corrected]

■ 2. On page 23456, in the first column, line 4, in § 615.5134(e), remove the term ''book'' and add in its place, the term ''market''.

Dated: May 1, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013–10820 Filed 5–7–13; 8:45 am]

BILLING CODE 6705–01–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: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places 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 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:* June 7, 2013.

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:

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 the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of HHS and on an evaluation of all other relevant data by DEA. This action imposes the regulatory controls and criminal sanctions of Schedule IV on the manufacture, distribution, dispensing, importation, and exportation of lorcaserin and products containing lorcaserin.

Background

Lorcaserin ((*R*)–8–chloro–1–methyl–2,3,4,5–tetrahydro–1*H*–3–benzepine hydrochloride hemihydrate) is a new

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

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

HHS and DEA Eight-Factor Analyses

On June 25, 2012, the Department of Human Health Service (HHS) provided to the Drug Enforcement Administration (DEA) a scientific and medical evaluation and scheduling recommendation entitled ''Basis for the Recommendation for Control of Lorcaserin in Schedule IV of the Controlled Substances Act.'' Following consideration of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that lorcaserin be controlled in Schedule IV of the CSA under 21 U.S.C. 812 (b).

In response, DEA conducted an eight-factor analysis of abuse potential of lorcaserin pursuant to 21 U.S.C. 811(c).

Determination to Schedule Lorcaserin

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from HHS, the Administrator of the DEA published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) entitled, ''Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV'' on December 19, 2012 (77 FR 75075), which proposed placement of lorcaserin into Schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before January 18, 2013.

Comments Received

DEA received seventy-one comments on the proposed rule to schedule lorcaserin. Commenters included individual health-care providers, national organizations, shareholders in the company which will market BELVIQ®, consultants, medical researchers, and other concerned citizens. There were 16 commenters in favor of the proposed rule and one opposed to it, with the remaining 54 commenters not taking a position.

Support of the Proposed Rule

Fifteen commenters supported controlling lorcaserin as a Schedule IV substance. Eleven commenters indicated support for controlling lorcaserin under the CSA based on the abuse potential of the substance. Most of the commenters supported the proposal to control lorcaserin as a Schedule IV substance. Because lorcaserin will be indicated as a weight loss drug, some commenters mentioned that there will be a high demand for the drug by the general public upon the drug being marketed. According to the commenters, controlling lorcaserin as a Schedule IV substance will therefore provide the necessary controls to prevent its diversion. Two commenters mentioned that weight loss drugs are needed in the United States.

DEA Response: DEA appreciates the support for this rulemaking.

Opposition to the Proposed Rule

Two commenters opposed the proposal to control lorcaserin as a Schedule IV substance. One commenter stated that lorcaserin should be controlled as a Schedule V substance, based on the commenter's stance that DEA is making assumptions of the abuse potential of lorcaserin. The commenter indicated that DEA did not include the methodology used to determine the abuse potential of lorcaserin. The other commenter stated that lorcaserin should be a non-controlled substance based on data from a published study on the abuse potential of lorcaserin in recreational polydrug users.[2]

DEA Response: DEA does not agree. The studies used to assess abuse potential of lorcaserin are widely held as the standard methods of evaluation. Clinical studies indicated that lorcaserin, similar to comparator drugs zolpidem (Schedule IV) and ketamine (Schedule III) produced significant increases on positive subjective measures (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 ARCI, compared to placebo. In a human abuse potential study, incidence of euphoria resulting from lorcaserin administration is similar to the incidence reported following zolpidem (Schedule IV) administration (13–16%) and lower than that following ketamine (Schedule III) administration (50%). The DEA did consider in its evaluation the published article [1] cited by the commenter. The data collectively suggest that lorcaserin does have sufficient abuse potential to warrant control under the CSA. HHS recommended control of lorcaserin in Schedule IV of the CSA and the DEA's placement findings support this level of control.

Requests To Control Lorcaserin in a Higher Schedule Than Schedule IV

Four commenters expressed concern that Schedule IV was not a stringent enough schedule for lorcaserin, based on it being an agonist at the $5–HT_{2A}$ receptors. These commenters suggested that lorcaserin be controlled in Schedule II or Schedule III. $5–HT_{2A}$ receptors mediate hallucinogenic properties of other drugs, such as lysergic acid diethylamide (LSD).

DEA Response: DEA believes that placement in Schedule IV of the CSA will help restrict unsafe access to lorcaserin and reduce instances of its abuse. Upon receiving from HHS a scientific and medical evaluation and a scheduling recommendation for lorcaserin, DEA also conducted its own analysis of the eight factors in accordance with 21 U.S.C. 811(b). Based on the review of HHS' evaluation and scheduling recommendation and other relevant data, DEA found that lorcaserin had a low potential for abuse relative to ketamine, a Schedule III drug, a currently accepted medical use for treatment in the United States, and that abuse of lorcaserin may lead to limited physical or psychological dependence relative to drugs in Schedule III. On the basis of these findings, lorcaserin is appropriately being controlled in Schedule IV.

Requests To Expedite the Lorcaserin Scheduling Action

There were thirty-two comments which requested that DEA expedite the scheduling action for lorcaserin. Generally, the commenters indicated that the scheduling action should be expedited due to epidemic levels of obesity in the United States and the absence of any weight loss drugs on the market with lorcaserin's novel mechanism of action. Some commenters stated that the review conducted by FDA was sufficient to justify that lorcaserin be controlled expeditiously. Of these thirty-two comments, seven comments also requested that, ''in the interest of public health,'' DEA waive the 30-day comment or implementation period in order to make lorcaserin available immediately. One commenter stated that the scheduling action should be expedited because ''based on scientific evidence that is available to date, there is no risk of this drug being addictive, and therefore abused.''

From the previously mentioned thirty-two comments, eight comments

[2] Shram et al. (2011) Clin Pharmacol Ther; 89(5):683–92.

requested that the placement of lorcaserin in Schedule IV become effective on the date of the publication of the Final Rule. One commenter requested that the implementation period be limited to two weeks instead of the standard 30 days. Generally the commenters stated that since obesity and obesity-related illnesses are occurring at epidemic levels, lorcaserin should be available to health care practitioners and patients in the immediate future. One commenter referenced other scheduling actions in which the effective date was the same as the publication date of the Final Rule as justification of doing the same for the lorcaserin. The scheduling actions referenced were zopiclone (70 FR 16935), pregabalin (70 FR 43633), and ezogabine (76 FR 77895).

DEA Response: DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with regulatory requirements for handling Schedule IV controlled substances. With regard to the comment about lack of abuse potential for lorcaserin, as mentioned in both HHS' and DEA's scientific and medical analyses, the data collectively suggest that lorcaserin does have sufficient abuse potential and though the effective dates for scheduling zopiclone, pregabalin, and ezogabine were the date of publication of their respective Final Rule, DEA does not agree that lorcaserin's effective date should be the date of publication of the Final Rule. The clinical indications of above referenced drugs are different from that of lorcaserin. DEA believes that the clinical indications for lorcaserin do not support the waiver of the 30-day period. With regard to the availability of weight-loss drugs, DEA further notes that other weight-loss drugs are currently available on the market.

Phentermine Being Combined With Lorcaserin

Eight commenters expressed concern about the probability that healthcare providers would prescribe phentermine with lorcaserin to increase weight loss results in patients.

DEA Response: Prescriptions for controlled substances, including lorcaserin, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. A determination of the validity of a prescription depends on an evaluation of the particular circumstances surrounding its issuance.

Risk Evaluations and Mitigation Strategy (REMS) Program for Lorcaserin

Three commenters stated that there should be a REMS program in place for the prescribing and dispensing of prescriptions of lorcaserin to minimize the misuse of lorcaserin. Two of these commenters also expressed concern about the effects of direct-to-consumer television advertisements of lorcaserin.

DEA Response: FDA is responsible for determining whether REMS programs should be implemented for particular drugs. Various agencies, such as FDA and the Federal Trade Commission (FTC), have a role in regulating direct-to-consumer drug advertising.

Request for a Hearing

One commenter requested a formal hearing prior to the finalization of the scheduling action for lorcaserin. The commenter expressed concern that the potential for abuse of lorcaserin is large since the indication is for the drug to be taken chronically for weight loss. The commenter requested that the hearing include ''relevant experts.''

DEA Response: DEA regulations provide that ''[a]ny interested person'' may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define ''interested person'' as ''any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811].'' 21 CFR 1300.01(b). The regulations further require that any person requesting a hearing must state ''with particularity'' his interest in the proceeding. 21 CFR 1316.47(a). Because the commenter failed to provide sufficient information to demonstrate that he meets the definition of ''interested person'' as set forth in the regulations, DEA hereby denies this hearing request.

Other Comments

The remaining comments were concerning various topics, not all of them being related to lorcaserin directly. The comments are summarized below as follows:

- Several commenters were critical of DEA's handling of the scheduling process. The commenters did not provide specific recommendations for action.
- One commenter expressed concern about the abuse potential of lorcaserin. The commenter did not indicate whether they opposed or supported the proposal to control lorcaserin.
- One commenter requested that DEA extend the comment period for the NPRM by 60 additional days. The commenter indicated that the public had not been given sufficient time to respond to the NPRM. DEA has allowed 30 days for a comment period in previous scheduling actions for new chemical entities. A 30-day comment period has been demonstrated to be a sufficient period to allow the public to submit comments to proposed scheduling actions.
- One commenter submitted information about Combo Pilling, which is not related to the current control action.
- One commenter discussed the side effects experienced with taking Qsymia, a weight loss drug. This comment was not related to the current scheduling action.
- Two commenters stated that obesity drugs are not needed to deal with the current obesity epidemic. This comment was not related to the current scheduling action.

Scheduling Conclusion

Based on consideration of all comments, 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 lorcaserin. As such, DEA will schedule lorcaserin as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as Schedules I, II, III, IV, and V. The statute outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), 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 Schedule IV substances such as zolpidem;

(2) Lorcaserin has a currently accepted medical use in treatment in the United States. Lorcaserin HCL 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 physical dependence or 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

Upon the effective date of this final rule, lorcaserin 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 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 research or conduct instructional activities with lorcaserin, must be registered to conduct such activities pursuant to 21 U.S.C. 822 and in accordance with 21 CFR Part 1301. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 7, 2013 and may not continue their activities until DEA has approved that application.

Security. Lorcaserin 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 on or after June 7, 2013.

Labeling and Packaging. All labels and labeling for commercial containers of lorcaserin must be in accordance with 21 CFR 1302.03–1302.07, pursuant to 21 U.S.C. 825, on or after June 7, 2013.

Inventory. Every registrant required to keep records and who possesses any quantity of lorcaserin must 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, 1304.06, and 1304.11 on or after June 7, 2013. Every registrant who desires registration in Schedule IV for lorcaserin is required to 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, 1304.21, 1304.22, and 1304.23 on or after June 7, 2013.

Prescriptions. All prescriptions for lorcaserin or prescriptions for products containing lorcaserin must comply with 21 U.S.C. 829 and 21 CFR 1306, including but not limited to 21 CFR 1306.03–1306.06, 1306.08, 1306.09, and 1306.21–1306.27 on or after June 7, 2013.

Importation and Exportation. All importation and exportation of lorcaserin must be done in accordance with 21 CFR Part 1312, pursuant to 21 U.S.C. 952, 953, 957, and 958, on or after June 7, 2013.

Criminal Liability. Any activity with lorcaserin not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after June 7, 2013.

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

Executive Order 13132

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

Executive Order 13175

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

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place lorcaserin, including its salts, isomers and salts of isomers, into Schedule IV of the CSA. By this final rule, lorcaserin will remain in Schedule IV unless and until additional scheduling action is taken to either transfer it between the schedules or to remove it from the list of schedules. See 21 U.S.C. 811 and 812. No less restrictive measures (i.e., non-control) enable DEA to meet its statutory obligations under the CSA.

Lorcaserin is a new chemical entity and is not currently available or marketed in any country. According to publicly available information reviewed by DEA, lorcaserin is anticipated to enjoy patent protection for at least a decade before generic equivalents may be manufactured and marketed. Accordingly, the number of currently identifiable manufacturers, importers, and distributors for lorcaserin is extremely small. The publicly available materials also specify the readily identifiable persons subject to direct regulation by this final rule. Based on guidelines utilized by the Small Business Administration, the lorcaserin manufacturer was identified as a small entity and is expected to conduct manufacturing activities at a facility outside the United States; the distributor/importer does not meet the standard as a small entity. Once generic equivalents are developed and approved for manufacturing and marketing, there may be additional manufacturers, importers, and distributors of lorcaserin, but whether they may qualify as small entity cannot be determined at this time.

There are approximately 1.4 million controlled substance registrants, approximately 381,000 of which are estimated to be businesses. DEA estimates that 371,000 (97%) of these businesses are considered ''small entities'' in accordance with the RFA and Small Business Administration standards. 5 U.S.C. 601(6) and 15 U.S.C. 632. However, due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the dispensing rates of new chemical entities, DEA is unable to determine the number of small entities which might dispense (including administer or prescribe) lorcaserin (e.g., pharmacies and prescribers).

Despite the fact that the number of small businesses possibly impacted by this rule could not be determined, DEA concludes that they would not experience a significant economic impact as a result of this rule. Currently

98% of DEA registrants (most of which are small businesses) are authorized to handle Schedule IV controlled substances. Even if we assume that all of these registrants were to handle lorcaserin (e.g., practitioners prescribe the substance, and pharmacies dispense those prescriptions), the costs that they would incur as a result of lorcaserin's scheduling would be nominal. Registrants that dispense (but not prescribe) would incur nominal additional security, inventory, recordkeeping, and labeling costs. These registered entities have already established and implemented these systems and processes required to handle Schedule IV controlled substances, and can easily absorb the costs of dispensing lorcaserin with nominal to no additional economic burden. For example, pharmacies and institutional practitioners may disperse Schedule II through V controlled substances throughout the stock of noncontrolled substances in such a manner as to obstruct theft or diversion of the controlled substances. In addition, because registered pharmacies must label all Schedule II through V controlled substances that they dispense, the requirement to label all dispensed substances containing lorcaserin would not impose a significant economic burden upon registered pharmacies. Accordingly, compliance would not require significant additional manpower, capital investment, or recordkeeping burdens.

The only additional requirement imposed by this rule upon registrants that only prescribe substances containing lorcaserin is that they issue an oral or written prescription to dispense the substance. Accordingly, registered prescribers would not incur any additional security, inventory, recordkeeping, or labeling costs as a result of this rule as they would not physically handle lorcaserin.

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

Unfunded Mandates Reform Act of 1995

For the reasons stated in the above section titled, ''Regulatory Flexibility Act,'' [3] this rule does not include a Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995 (UMRA).

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.

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 for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets. However, pursuant to the CRA, DEA has submitted a copy of this Final Rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by Section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100) the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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.

■ 1. 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: April 29, 2013.

Michele M. Leonhart,

Administrator.

[FR Doc. 2013–10895 Filed 5–7–13; 8:45 am]

BILLING CODE 4410–09–P

[3] UMRA and the RFA share the same definition of ''rule.'' UMRA defines ''regulation'' or ''rule'' by cross-referencing the RFA's definition of ''rule.'' 2 U.S.C. 658(10)). The RFA generally defines ''rule'' as ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of [the Administrative Procedure Act].'' 5 U.S.C. 601(2).

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 09–197; 11–42; FCC 13–44]

Telecommunications Carriers Eligible for Support; Lifeline and Link Up Reform and Several Petitions for Forbearance

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this order, the Federal Communications Commission (Commission) grants limited forbearance from the requirement of the Commission's rules that the service area of an eligible telecommunications carrier (ETC) conform to the service area of any rural telephone company serving the same area. In particular, this grant of forbearance applies to any ETC that has been designated by a state or the Commission, as well as pending and future requests by telecommunications carriers that seek limited designation, as an ETC to participate only in the Lifeline program (Lifeline-only ETC). The Commission concludes that forbearance furthers the Act's and Commission's goals of ensuring the availability of voice service to low-income consumers.

DATES: Effective June 7, 2013, except paragraph 19 which is effective upon release of the Memorandum Opinion and Order.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau, (202) 418–0428 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Memorandum Opinion and Order (Order) in WC Docket Nos. 09–197;11–42; FCC 13–44, released on April 15, 2013. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554. Or at the following Internet address: