

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meeting was widely publicized throughout the Florida tomato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the October 4, 2006, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

An interim final rule concerning this action was published in the **Federal Register** on February 6, 2007. Copies of the rule were mailed by the Committee's staff to all Committee members and tomato handlers. In addition, the rule was made available through the Internet by USDA and the Office of the **Federal Register**. That rule provided for a 60-day comment period which ended April 9, 2007. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the Committee's recommendation, and other information, it is found that finalizing the interim final rule, without change, as published in the **Federal Register** (72 FR 5327, February 6, 2007) will tend to effectuate the declared policy of the Act.

#### List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

#### PART 966—TOMATOES GROWN IN FLORIDA

■ Accordingly, the interim final rule amending 7 CFR part 966 which was published at 72 FR 5327 on February 6, 2007, is adopted as a final rule without change.

Dated: April 27, 2007.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E7-8459 Filed 5-2-07; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-301F]

#### Schedules of Controlled Substances: Placement of Lisdexamfetamine Into Schedule II

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

**ACTION:** Final Rule.

**SUMMARY:** With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance lisdexamfetamine, including its salts, isomers and salts of isomers into schedule II of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation and exportation of lisdexamfetamine and products containing lisdexamfetamine.

**EFFECTIVE DATE:** June 4, 2007.

#### FOR FURTHER INFORMATION CONTACT:

Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

#### SUPPLEMENTARY INFORMATION:

Lisdexamfetamine is a central nervous system stimulant drug. On February 23, 2007, the Food and Drug Administration (FDA) approved lisdexamfetamine for marketing under the trade name Vyvanse™. Lisdexamfetamine will be marketed as a prescription drug product for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Lisdexamfetamine is an amide ester conjugate comprised of the amino acid L-lysine covalently bound to the amino group of d-amphetamine. The chemical name of its dimesylate salt form is (2S)-2,6-diamino-N-[(1S)-1-methyl-2-phenethyl]hexanamide dimethanesulfonate (CAS number 608137-32-3). Lisdexamfetamine per se is pharmacologically inactive and its effects are due to its in vivo metabolic conversion to d-amphetamine.

Lisdexamfetamine is a new molecular entity and has not been marketed in the United States or other countries. Therefore, there has been no evidence of diversion, abuse, or law enforcement encounters involving lisdexamfetamine.

On November 14, 2006, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a

scientific and medical evaluation and a letter recommending that lisdexamfetamine be placed into schedule II of the CSA. Enclosed with the November 14, 2006, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Lisdexamfetamine in Schedule II of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a February 22, 2007, Notice of Proposed Rulemaking (72 FR 7945), proposed placement of lisdexamfetamine into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments to be postmarked and electronic comments be sent on or before March 26, 2007.

#### Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One commenter stated that monthly visits to obtain refills for Concerta [supreg]—like drugs used in children are very expensive and the law needs to be changed. DEA notes that statutory requirements for schedule II drugs do not permit prescription refills. DEA does not regulate the size of each prescription or the frequency of medical visits; these matters are within the purview of prescribing physician. DEA has no authority regarding either the cost of medical care or the cost of the medications a prescribing practitioner may prescribe. Another commenter requested the name of the company that filed the New Drug Application for lisdexamfetamine in order to obtain standard analytical reference material and/or analytical data from the company. This comment is not relevant to the present scheduling action.

#### Scheduling of Lisdexamfetamine

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Lisdexamfetamine has a high potential for abuse;

(2) Lisdexamfetamine has a currently accepted medical use in treatment in the United States; and

(3) Abuse of lisdexamfetamine may lead to severe psychological or physical dependence.

Based on these findings, the Deputy Administrator of DEA concludes that lisdexamfetamine, including its salts, isomers, and salts of isomers, warrants control in schedule II of the CSA. The applicable regulations are as follows:

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with lisdexamfetamine, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lisdexamfetamine, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations. 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 4, 2007 and may continue their activities until DEA has approved or denied that application.

**Security.** Lisdexamfetamine is subject to schedule II security requirements and must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Labeling and Packaging.** All labels and labeling for commercial containers of lisdexamfetamine must comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Quotas.** Quotas for lisdexamfetamine must be established pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

**Inventory.** Every registrant required to keep records and who possesses any quantity of lisdexamfetamine must keep an inventory of all stocks of lisdexamfetamine on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after June 4, 2007. Every registrant who desires registration in schedule II for lisdexamfetamine must conduct an inventory of all stocks of the substance on hand at the time of registration.

**Records.** All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Reports.** All registrants required to submit reports to the Automation of Reports and Consolidated Order System (ARCOS) in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations must do so for lisdexamfetamine.

**Orders for Lisdexamfetamine.** All registrants involved in the distribution of lisdexamfetamine must comply with the order requirements of part 1305 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Prescriptions.** All prescriptions for lisdexamfetamine or prescriptions for products containing lisdexamfetamine must be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.11–1306.15.

**Importation and Exportation.** All importation and exportation of lisdexamfetamine must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after June 4, 2007.

**Criminal Liability.** Any activity with lisdexamfetamine 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 4, 2007.

## Regulatory Certifications

### Executive Order 12866

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 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

### Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), 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. Lisdexamfetamine products will be prescription drugs used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Handlers of lisdexamfetamine also handle other controlled substances used to treat ADHD which are already subject to the regulatory requirements of the CSA.

### 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.

### Executive Order 13132

This 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.

### 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 \$120,000,000 or more 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.

### Congressional Review Act

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

### List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ 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), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 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 1308.12 is amended by adding a new paragraph (d)(5) to read as follows:

### § 1308.12 Schedule II.

\* \* \* \* \*

(d) \* \* \*

(5) Lisdexamfetamine, its salts, isomers, and salts of its isomers—1205.

\* \* \* \* \*

Dated: April 25, 2007.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[CGD05-07-047]

RIN 1625-AA-09

#### Drawbridge Operation Regulations; Intracoastal Waterway (ICW); Inside Thorofare, Atlantic City, NJ

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the U.S. 40-322 (Albany Avenue) Bridge, at ICW mile 70.0, across Inside Thorofare at Atlantic City, New Jersey. This deviation allows the drawbridge to remain closed-to-navigation from 10 a.m. to 5 p.m. on August 15, 2007, to facilitate traffic control during the Atlantic City Air Show.

**DATES:** This deviation is effective from 10 a.m. to 5 p.m. on August 15, 2007.

**ADDRESSES:** Materials referred to in this document are available for inspection or copying at Commander (dpb), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704-5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6222. Commander (dpb), Fifth Coast Guard District maintains the public docket for this temporary deviation.

**FOR FURTHER INFORMATION CONTACT:** Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, at (757) 398-6222.

**SUPPLEMENTARY INFORMATION:** The U.S. 40-322 (Albany Avenue) Bridge, a lift drawbridge, has a vertical clearance in the closed position to vessels of 10 feet, above mean high water.

The Atlantic City Regional Mainland Chamber of Commerce, on behalf of the bridge owner the New Jersey Department of Transportation, has requested a temporary deviation from

the current operating regulation set out in 33 CFR 117.733(f) to close the drawbridge to navigation for the sole purpose of traffic control during the Atlantic City Air Show that is scheduled for Wednesday, August 15, 2007.

To facilitate traffic control during the Atlantic City Air Show, the U.S. 40-322 (Albany Avenue) Bridge will be maintained in the closed-to-navigation position from 10 a.m. to 5 p.m. on August 15, 2007.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 24, 2007.

**Waverly W. Gregory, Jr.,**

*Chief, Bridge Administration Branch, Fifth Coast Guard District.*

[FR Doc. E7-8493 Filed 5-2-07; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD08-07-010]

RIN 1625-AA11

#### Regulated Navigation Area; Cumberland River, Clarksville, TN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a Regulated Navigation Area (RNA) on the Cumberland River (CMR) mile marker (MM) 126 to mile marker MM 127. All vessel traffic transiting beneath the R.J. Corman Railroad Bridge at MM 126.5 is restricted to the right descending bank (RDB) on the CMR and tows transiting this RNA cannot be wider than 80 feet or longer than 800 feet, excluding the length of the tow boat.

**DATES:** This temporary rule is effective from 4:40 p.m. on March 31, 2007 through 11:30 a.m. August 2, 2007.

**ADDRESSES:** The Coast Guard is not soliciting comments on this temporary RNA. However, you may mail comments and related material to Coast Guard Sector Ohio Valley, 600 Martin Luther King Drive, Louisville, KY 40202, attention: Prevention Department. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Coast Guard Sector Ohio Valley between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** CDR Greg Howard, Coast Guard Sector Ohio Valley, telephone (502) 779-5422.

### SUPPLEMENTARY INFORMATION:

#### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 United States Code (USC) 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM and under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective immediately. The R.J. Corman Railroad Bridge on the Cumberland River was struck by a barge and was severely damaged. This RNA is needed to prevent further damage to the bridge and to protect vessels transiting under the bridge.

#### Background and Purpose

On March 29, 2007 at approximately 11:15 p.m., the R.J. Corman Railroad Bridge, located at MM 126.5 on the Cumberland River (CMR) was struck by a barge being pushed by a towing vessel. The bridge sustained extensive damage. The Coast Guard set a safety zone at 7 p.m. on March 30, 2007 on the CMR from MM 126 through MM 127 halting all vessel traffic until the structural integrity of the bridge was evaluated. The operator of the bridge reported to the Coast Guard that the bridge damage was isolated to the left descending bank (LDB) bridge pier of the bridge above the waterline. The bridge operator also informed the Coast Guard that vessels could safely transit under the bridge on the right descending bank (RDB) of the CMR. The Coast Guard is restricting vessel movements to the RDB and is limiting tow sizes to ensure that vessels pass safely under the bridge and do not cause additional damage to the bridge.

#### Discussion of Rule

The Coast Guard is establishing a Regulated Navigation Area (RNA) on the CMR mile marker (MM) 126 to mile marker MM 127. All vessel traffic transiting beneath the R.J. Corman Railroad Bridge at MM 126.5 is restricted to the RDB on the CMR and tows transiting this RNA cannot be wider than 80 feet or longer than 800 feet, excluding the length of the tow boat. This RNA is effective from 4:40 p.m. on March 31, 2007 through 11:30 a.m. August 2, 2007. This RNA may be cancelled earlier if the Coast Guard determines that it is safe for vessel traffic to transit under the bridge span adjacent to the LDB.