AMOCs for the corresponding provisions of this AD.

(6) AMOCs approved previously for the repetitive lubrications required by AD 2015–12–03, are approved as AMOCs for the corresponding provisions of this AD.

(n) Related Information

(1) For more information about this AD, contact Luis Cortez-Muniz, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone: (206) 231–3958; email: *Luis.A.Cortez-Muniz@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(5) and (6) of this AD.

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on October 12, 2022 (87 FR 54609, September 7, 2022).

(i) Boeing Special Attention Service Bulletin 777–27–0062, Revision 4, dated July 15, 2021.

(ii) [Reserved]

(4) The following service information was approved for IBR on July 21, 2015 (80 FR 34252, June 16, 2015).

(i) Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014.

(ii) [Reserved]

(5) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

(6) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 23, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–21021 Filed 9–29–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–949]

Schedules of Controlled Substances: Placement of Daridorexant in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without change an interim final rule with request for comments published in the **Federal Register** on April 7, 2022, placing daridorexant ([(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible, in schedule IV of the Controlled Substances Act (CSA). With the issuance of this final rule, the Drug Enforcement Administration maintains daridorexant in schedule IV of the CSA.

DATES: The effective date of this rulemaking is October 31, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule (IFR), with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and to subsequently issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On January 7, 2022, DEA received notification that the United States Food and Drug Administration (FDA) approved, on the same date, a new drug application (NDA) for QUVIVIQ (daridorexant) tablets for use as a treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Daridorexant, chemically known as [(S)-2-(5-chloro-4-methyl-1*H*-benzo[*d*]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2*H*-1,2,3-triazol-2-yl)phenyl)methanone, is a new molecular entity (NME) with central nervous system activity. Previously, on December 22, 2021, DEA received HHS's recommendation that DEA place daridorexant and ''its salts'' in schedule IV of the CSA, in the event that FDA approves the NDA for daridorexant. On April 7, 2022, DEA, pursuant to 21 U.S.C. 811(j), published an IFR (87 FR 20313) to place daridorexant (including its salts, isomers, and salts of isomers) in schedule IV of the CSA; the regulatory text only listed the chemical name for daridorexant. In the preamble of the IFR, DEA incorrectly misspelled the proprietary name for daridorexant's approved drug product as ''QUIVIVIQ.'' The preamble of this final rule now correctly uses ''QUVIVIQ.'' It bears emphasis that the regulatory text used in this final rule remains unchanged from that used in the IFR.

The IFR provided an opportunity for interested persons to submit comments, as well as to file a request for hearing or waiver of hearing, on or before May 9, 2022. DEA did not receive any requests for hearing or waivers of hearing.

Comment Received

In response to the IFR, DEA received one comment. The submission was from an anonymous commenter. The commenter supported the placement of daridorexant in schedule IV of the CSA, and noted its safety, effectiveness, and approved indication for use as a treatment of patients with insomnia.

DEA Response: DEA appreciates the support for this rulemaking.

Requirements for Handling Daridorexant

As indicated above, daridorexant has been a schedule IV controlled substance by virtue of an IFR issued by DEA on April 7, 2022. Thus, this final rule does not alter the regulatory requirements applicable to handlers of daridorexant that have been in place since that time. Nonetheless, for informational purposes, DEA restates here those requirements. Daridorexant is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the

manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) daridorexant, or who desires to handle daridorexant, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle daridorexant and is not registered with DEA must submit an application for registration and may not handle daridorexant unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. These registration requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person who obtains a schedule IV registration to handle daridorexant but who subsequently does not desire or is not able to maintain such registration must surrender all quantities of daridorexant, or may transfer all quantities of daridorexant to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Daridorexant is subject to schedule III–V security requirements for DEA registrants and must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling daridorexant must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93. These requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of daridorexant must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. *Inventory.* Every DEA registrant who possesses any quantity of daridorexant was required to keep an inventory of daridorexant on hand, as of April 7, 2022, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. These requirements, however, are not applicable to patients (end users) who possess daridorexant pursuant to a lawful prescription.

6. *Records and Reports.* DEA registrants must maintain records and submit reports for daridorexant, pursuant to 21 U.S.C. 827 and 832(a), and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b) and parts 1304, 1312, and 1317.

7. *Prescriptions.* All prescriptions for daridorexant, or products containing daridorexant, must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR parts 1306 and 1311, subpart C.

8. *Manufacturing and Distributing.* In addition to the general requirements of the CSA and DEA regulations that are applicable to manufacturers and distributors of schedule IV controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of daridorexant may only be for the legitimate purposes consistent with the drug's labeling, or for research activities authorized by the Federal Food, Drug, and Cosmetic Act (FDCA), as applicable, and the CSA.

9. *Importation and Exportation.* All importation and exportation of daridorexant must comply with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving daridorexant not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Administrative Procedure Act

This final rule adopts, without change, the amendment made by the IFR that is already in effect. Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an IFR scheduling the drug within 90 days. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an IFR without requiring DEA to demonstrate good cause. DEA issued an IFR on April 7, 2022, and solicited public comments on that rule. Subsection (j) further states that after giving interested persons the opportunity to comment and to request a hearing, the Attorney General, as delegated to the Administrator of DEA, shall issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b). DEA is now responding to the comment submitted by the public and issuing the final rule, in accordance with 21 U.S.C. 811(j).

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a) and (j), this scheduling action is subject to formal rulemaking procedures performed ''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 procedures and 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 (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 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, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This final rule does not have tribal implications warranting the application of E.O. 13175. It 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general notice

of proposed rulemaking. Consequently, the RFA does not apply.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any 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 annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA 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.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to the Government Accountability Office, the House, and the Senate under the CRA.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 26, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

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

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ Accordingly, the interim final rule (87 FR 20313) amending 21 CFR part 1308, which published on April 7, 2022, is adopted as a final rule without change.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022–21253 Filed 9–29–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2022–0371]

RIN 1625–AA09

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway (AICW) and Miami Beach Channel, Miami, FL

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the West 79th Street Bridge crossing the Atlantic Intracoastal Waterway (AICW), mile 1084.6 at Miami, Florida, and the East 79th Street Bridge crossing Miami Beach Channel, mile 2.20 at Miami Beach, Florida. North Bay Village requested the Coast Guard consider placing additional weekday restrictions during rush hour on both drawbridges to assist with alleviating vehicle congestion. This deviation will test a proposed change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding these proposed changes.

DATES: This deviation is effective from 12:01 a.m. on October 1, 2022, through 11:59 p.m. on March 29, 2023.

Comments and relate material must reach the Coast Guard on or before December 29, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0371 using Federal Decision Making Portal at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this test deviation, call or email Ms. Jennifer Zercher, Bridge Management Specialist, Seventh Coast Guard District; telephone 305–415–6740, email *Jennifer.N.Zercher@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The West 79th Street Bridge crossing the AICW, mile 1084.6, at Miami, FL, is a double-leaf bascule bridge with a 21 foot vertical clearance (25 feet charted at the center span) at mean high water in the closed position. The normal operating schedule for the bridge is set forth in 33 CFR 117.261 (mm-1). The East 79th Street Bridge crossing the Miami Beach Channel, mile 2.20, at Miami Beach, FL, is a double-leaf bascule bridge with a 21 foot vertical clearance at mean high water in the closed position. The normal operating schedule for the bridge is set forth in 33 CFR 117.304. Navigation on the waterways consists of recreational and commercial mariners.

North Bay Village with the support of the bridge owner, Florida Department of Transportation (FDOT), requested the Coast Guard consider allowing the drawbridges to remain closed to navigation during morning and evening rush hour with top of the hour openings provided at pre-determined times. North Bay Village is requesting this change to assist with alleviating vehicle traffic in the area.

On June 7, 2022, the Coast Guard published a notice of proposed rulemaking entitled, ''Drawbridge Operation Regulation; Atlantic Intracoastal Waterway (AICW) and Miami Beach Channel, Miami, FL'' in the **Federal Register** (87 FR 34601). We received one hundred twenty-six comments. Those comment will be addressed during the rulemaking.

Under this test deviation both drawbridges shall operate as follows, Monday through Friday, except Federal holidays, both drawbridges need only open on the hour between 7 a.m. and 10 a.m. Between 10 a.m. and 4 p.m., both drawbridges need only open on the hour and half hour. From 4 p.m. to 7 p.m., both drawbridges need only open on the hour. From 7 p.m. to 7 a.m., both drawbridges shall open on signal. Saturday, Sunday, and Federal holidays, both drawbridges shall open on signal. Vessels that can pass beneath the drawbridges without an opening may do so at any time.

The Coast Guard will also inform waterway users of the temporary change to the operating schedules via the Local and Broadcast Notice to Mariners so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.