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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2022-0148; Project Identifier AD-2021-00922-T; Amendment 39-22110; AD 2022-14-05]

RIN 2120-AA64

#### Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** The FAA is correcting an airworthiness directive (AD) that was published in the *Federal Register*. That AD superseded AD 2015-12-03, and applies to all The Boeing Company Model 777-200, -200LR, -300, and -300ER series airplanes, and certain Model 777F airplanes. As published, a freeplay indicator value in the regulatory text is incorrect, and certain credit service information was omitted for certain actions in the regulatory text. This document corrects those errors. In all other respects, the original document remains the same.

**DATES:** This correction is effective October 12, 2022. The effective date of AD 2022-14-05 remains October 12, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 12, 2022 (87 FR 54609, September 7, 2022).

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of July 21, 2015 (80 FR 34252, June 16, 2015).

#### ADDRESSES:

*AD Docket:* You may examine the AD docket at [regulations.gov](https://www.regulations.gov) by searching for and locating Docket No. FAA-2022-0148; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday

through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The street address for Docket Operations is listed above.

#### Material Incorporated by Reference:

- For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110-SK57, Seal Beach, CA 90740-5600; telephone 562-797-1717; website [myboeingfleet.com](https://myboeingfleet.com).

- You may view this referenced 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. It is also available at [regulations.gov](https://www.regulations.gov) by searching for and locating Docket No. FAA-2022-0148.

**FOR FURTHER INFORMATION 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](mailto:Luis.A.Cortez-Muniz@faa.gov).

**SUPPLEMENTARY INFORMATION:** AD 2022-14-05, Amendment 39-22110 (87 FR 54609, September 7, 2022) (AD 2022-14-05), superseded AD 2015-12-03, Amendment 39-18176 (80 FR 34252, June 16, 2015) (AD 2015-12-03). AD 2022-14-05 retains the requirements for repetitive freeplay inspections and lubrication of the right and left elevators, rudder, and rudder tab, and related investigative and corrective actions if necessary. AD 2022-14-05 also requires revising the existing maintenance or inspection program, as applicable, for certain other airplanes, to incorporate a revised or new elevator freeplay maintenance procedure, as applicable. AD 2022-14-05 applies to all The Boeing Company Model 777-200, -200LR, -300, and -300ER series airplanes, and certain Model 777F airplanes.

#### Need for Correction

As published, paragraphs (j)(3) and (l) of AD 2022-14-05 are incorrect.

Paragraph (j)(3) of AD 2022-14-05 requires incorporating a revision of the elevator freeplay dial indicator limit to "0.34 in. (152 mm) or less." The correct value is "0.34 in. (8.636 mm) or less."

Additionally, paragraph (l) of AD 2022-14-05 inadvertently omitted credit for certain actions that was previously provided in AD 2015-12-03 for the following service information: Boeing Special Attention Service Bulletin 777-27-0062, dated July 18, 2006, and Revision 1, dated October 1, 2009. The FAA intended for that service information to be retained as credit for the corresponding retained actions in AD 2022-14-05.

#### Related Service Information Under 14 CFR Part 51

The FAA reviewed Boeing Special Attention Service Bulletin 777-27-0062, Revision 4, dated July 15, 2021. This service information specifies procedures for changing the elevator freeplay instructions by adding changes to the input force, elevator freeplay limit, and power control unit (PCU) bypass test setup.

This AD also requires Boeing Special Attention Service Bulletin 777-27-0062, Revision 2, dated January 27, 2014, which the Director of the Federal Register approved for incorporation by reference as of July 21, 2015 (80 FR 34252, June 16, 2015).

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

#### Correction of Publication

This document corrects two errors and correctly adds the AD as an amendment to 14 CFR 39.13. Although no other part of the preamble or regulatory information has been corrected, the FAA is publishing the entire rule in the *Federal Register*.

The effective date of this AD remains October 12, 2022.

Since this action only corrects a freeplay indicator value and adds credit service information, it has no adverse economic impact and imposes no additional burden on any person. Therefore, the FAA has determined that notice and public comment procedures are unnecessary.

#### List of Subjects in 14 CFR Part 39

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

## Adoption of the Correction

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) by correcting 87 FR 54609 (September 7, 2022), beginning at page 54611, column 1, 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 [Corrected]

■ 2. The FAA amends § 39.13 by:

- a. Removing Airworthiness Directive (AD) 2015–12–03, Amendment 39–18176 (80 FR 34252, June 16, 2015); and
- b. Adding the following new AD:

#### 2022–14–05 The Boeing Company:

Amendment 39–22110; Docket No. FAA–2022–0148; Project Identifier AD–2022–00922–T.

#### (a) Effective Date

This airworthiness directive (AD) is effective October 12, 2022.

#### (b) Affected ADs

This AD replaces AD 2015–12–03, Amendment 39–18176 (80 FR 34252, June 16, 2015) (AD 2015–12–03).

#### (c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (2) of this AD.

(1) All Model 777–200, –200LR, –300, and –300ER series airplanes.

(2) Model 777F airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before the effective date of this AD.

#### (d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

#### (e) Unsafe Condition

This AD was prompted by the manufacturer's determination that the procedure for the rudder freeplay inspection available at the time did not properly detect excessive freeplay in the rudder control load loop. This AD was also prompted by engineering testing that revealed that the force being applied to the elevator to detect excessive freeplay was insufficient. The FAA is issuing this AD to address excessive wear in the load loop components of the control surfaces, which could lead to excessive freeplay of the control surfaces, flutter, and consequent loss of control of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Retained Repetitive Inspections of Elevators, Rudder, and Rudder Tab, With Revised Service Information

This paragraph restates the requirements of paragraph (g) of AD 2015–12–03, with revised service information. For Model 777–200, –200LR, –300, and –300ER series airplanes: At the applicable times specified in tables 1, 2, and 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021, except as provided by paragraph (i)(1) of this AD: Inspect the freeplay of the right and left elevators, rudder, and rudder tab by accomplishing all of the actions specified in Parts 1, 3, and 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021, except as provided by paragraphs (i)(2) through (5) of this AD. Repeat the inspections thereafter at the intervals specified in tables 1, 2, and 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021. If, during any inspection required by this paragraph, the freeplay exceeds any applicable measurement specified in Part 1, 3, and 5, as applicable, of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021, before further flight, do the applicable corrective actions in accordance with Part 1, 3, and 5 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021. After the effective date of this AD use only Boeing Special Attention Service Bulletin 777–27–0062, Revision 4, dated July 15, 2021.

#### (h) Retained Repetitive Lubrication, With Revised Service Information

This paragraph restates the requirements of paragraph (h) of AD 2015–12–03, with revised service information. For Model 777–200, –200LR, –300, and –300ER series airplanes: At the applicable times specified in tables 1, 2, and 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021, except as provided by paragraph (i)(1) of this AD: Lubricate the elevator components, rudder components, and rudder tab components, by accomplishing all of the actions specified in Parts 2, 4, and 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021. Repeat the lubrication thereafter at the interval specified in tables 1, 2, and 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, or Revision 4, dated July 15, 2021. After the effective date of this AD use only Boeing Special Attention Service Bulletin 777–27–0062, Revision 4, dated July 15, 2021.

#### (i) Exceptions To Service Information Specifications, With Revised Service Information and a New Exception

This paragraph restates the requirements of paragraph (i) of AD 2015–12–03, with revised service information and a new exception, for Model 777–200, –200LR, –300, and –300ER series airplanes.

(1) Where Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, and Revision 4, dated July 15, 2021, specify a compliance time “after the original issue date on this service bulletin,” this AD requires compliance within the specified compliance time after July 25, 2007 (the effective date of AD 2007–13–05, Amendment 39–15109 (72 FR 33856, June 20, 2007)). After the effective date of this AD, only Boeing Special Attention Service Bulletin 777–27–0062, Revision 4, dated July 15, 2021, may be used.

(2) Where Appendix B, paragraph 1.f., “Freeplay Inspection,” step (8), of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, specifies that the center of the pad must be within 1.0 inch (13 millimeters) of the center line of the rib rivets in the rudder tab, this AD requires that the center of the tab must be within 1.0 inch (25 millimeters) of the center line of the rib rivets in the rudder tab.

(3) Where Appendix C, paragraph 1.e., “Rudder Tab Surface Freeplay–Inspection,” step (2) and step (6), of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, specify that the placement of the force gage and pad should be within one inch of the centerline line of the middle rudder power control unit (PCU) rib and at  $12 \pm 1$  inch ( $305 \pm 72$  millimeters) forward of the rudder tab trailing edge, this AD requires placement of the force gage and pad within one inch of the centerline line of the middle rudder PCU rib and at  $12 \pm 1$  inch ( $305 \pm 25$  millimeters) forward of the rudder tab trailing edge.

(4) Where Appendix C, paragraph 1.e., “Rudder Tab Surface Freeplay–Inspection,” step (3), of Boeing Special Attention Service Bulletin 777–27–0062, Revision 2, dated January 27, 2014, specifies to apply a  $30 \pm$  pound ( $133 \pm 14$  newton) force, this AD requires applying a  $30 \pm 3$  pound force ( $133 \pm 14$  newton) force.

(5) Where the CAUTION note just before step (6) of Appendix A, paragraph 1.f., “Freeplay Inspection,” of Boeing Special Attention Service Bulletin 777–27–0062, Revision 4, dated July 15, 2021, specifies using a pad that distributes the force over an area of 84 square inches (5,420 square centimeters) or more, this AD requires using a pad that distributes the force over an area of 84 square inches (542 square centimeters) or more.

#### (j) New Maintenance or Inspection Program Revision

For Model 777F airplanes: Within 30 days after the effective date of this AD, revise the 777F elevator freeplay maintenance procedure in the existing maintenance or inspection program, as applicable, by doing the actions specified in paragraphs (j)(1) through (3) of this AD.

(1) Remove the existing hydraulic depressurization PCU test setup procedure

step and replace it by incorporating the information specified in figure 1 to paragraph (j) of this AD.

(2) Revise the jack test force used to push the elevator up to  $225 \pm 10$  lb ( $102.1 \pm 4.5$  kg).

(3) Revise the elevator freeplay dial indicator limit to 0.34 in. (8.636 mm) or less.

**Figure 1 to paragraph (j): Circuit breaker elevator freeplay test setup**

Do these steps to prepare for the freeplay inspection:

NOTE: Each PCU can be inspected in any order, as long as the setup for the inspection is performed per the steps below.

a) To inspect the left elevator outboard PCU, do these steps:

1. Open this circuit breaker and install safety tag:

**Power Supply Assembly Center, M24301**

<u>Row</u>	<u>Col</u>	<u>Number</u>	<u>Name</u>
A	7	CBA7-C	ELEV PCU

2. Make sure that the left elevator inboard PCU is in bypass mode

b) To inspect the left elevator inboard PCU, do these steps:

1. Open this circuit breaker and install safety tag:

**Power Supply Assembly Left, M24101**

<u>Row</u>	<u>Col</u>	<u>Number</u>	<u>Name</u>
A	7	CBA7-L	ELEV PCU

2. Make sure that the left elevator outboard PCU is in bypass mode.

c) To inspect the right elevator inboard PCU, do these steps:

1. Open this circuit breaker and install safety tag:

**Left Power Management Panel, P110**

<u>Row</u>	<u>Col</u>	<u>Number</u>	<u>Name</u>
K	27	C27609	ELEV PCU RIB (BLK)/ROB(BYP)

2. Make sure that the right elevator outboard PCU is in bypass mode.

d) To inspect the right elevator outboard PCU, do these steps:

1. Open this circuit breaker and install safety tag:

**Power Supply Assembly Right, M24201**

<u>Row</u>	<u>Col</u>	<u>Number</u>	<u>Name</u>
A	7	CBA7-R	ELEV PCU

2. Make sure that the right elevator inboard PCU is in bypass mode.

**Note 1 to paragraph (j):** Refer to AMM task 27-31-09-200-801, dated September 5, 2021, for additional guidance.

**(k) No Alternative Actions or Intervals**

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m) of this AD.

**(l) Credit for Previous Actions**

(1) This paragraph provides credit for the actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before July 21, 2015 (the effective date of AD 2015-12-03) using the service information specified in paragraphs (l)(1)(i) or (ii) of this AD.

(i) Boeing Special Attention Service Bulletin 777-27-0062, dated July 18, 2006, which was incorporated by reference in AD

2007-13-05, Amendment 39-15109 (72 FR 33856, June 20, 2007).

(ii) Boeing Special Attention Service Bulletin 777-27-0062, Revision 1, dated October 1, 2009, which is not incorporated by reference in this AD.

(2) This paragraph provides credit for the actions specified in paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 777-27-0062, Revision 3, dated October 9, 2015, which is not incorporated by reference in this AD.

**(m) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (n)(1) of

this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for the freeplay measurements of the right and left rudder tab required by AD 2015-12-03, are approved as AMOCs for the corresponding provisions of this AD.

(5) AMOCs approved previously for the freeplay measurements of the rudder required by AD 2015-12-03, are approved as

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](mailto: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 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website [myboeingfleet.com](http://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](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://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-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl)(5-methoxy-2-(2H-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-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl](5-methoxy-2-(2H-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