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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1645]

Schedules of Controlled Substances: Rescheduling of Suvorexant, Lemborexant, and Daridorexant from Schedule IV into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes to transfer suvorexant ([(7*R*)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl]-[5-methyl-2-(triazol-2-yl)phenyl]methanone), lemborexant ((1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide), and daridorexant ([(2*S*)-2-(5-chloro-4-methyl-1*H*-benzimidazol-2-yl)-2-methylpyrrolidin-1-yl]-[5-methoxy-2-(triazol-2-yl)phenyl]methanone) from schedule IV to schedule V of the Controlled Substances Act. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule V controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle suvorexant, lemborexant, and daridorexant.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 and/or 1316.49, as applicable. Requests

for a hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received or postmarked on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference "Docket No. DEA-1645" on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit comments electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the webpage or attach a file for lengthier comments. Please go to */www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number. Submitted comments are not instantaneously available for public view on *www.regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

- *Paper comments:* Paper comments that duplicate the electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent

to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

As required by 5 U.S.C. 553(b)(4), a summary of this rule may be found in the docket for this rulemaking at *www.regulations.gov*.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) proposes to transfer suvorexant ([(7*R*)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl]-[5-methyl-2-(triazol-2-yl)phenyl]methanone), lemborexant ((1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide), and daridorexant ([(2*S*)-2-(5-chloro-4-methyl-1*H*-benzimidazol-2-yl)-2-methylpyrrolidin-1-yl]-[5-methoxy-2-(triazol-2-yl)phenyl]methanone) from schedule IV to schedule V of the Controlled Substances Act (CSA).

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at *https://www.regulations.gov*, unless reasonable cause is given. Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made

publicly available should submit two copies of the comment. One copy must be marked "CONTAINS CONFIDENTIAL INFORMATION" and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked "TO BE PUBLICLY POSTED" and must have all claimed confidential or proprietary business information redacted. DEA will post only the redacted comment on *https://www.regulations.gov* for public inspection. DEA generally will not redact additional information contained in the comment marked "TO BE PUBLICLY POSTED." The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed rule are available at *https://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA).[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person regarding the objections or issues.

[1] 5 U.S.C. 551-559; 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the *Federal Register*.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether suvorexant, lemborexant, and daridorexant meet the statutory criteria in 21 U.S.C. 812(b)(5) to transfer these substances from schedule IV to schedule V, as proposed in this rule.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of the Department of Health and Human Services (HHS), or on the petition of an interested party.[4] This proposed action was initiated by DEA,[5] and it is supported by, *inter alia*,

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[2] 21 CFR 1316.49.
[3] 21 CFR 1308.44(b), 1316.53.
[4] 21 U.S.C. 811(a).
[5] On April 3, 2023, Idorsia Pharmaceutical Limited submitted a petition requesting DEA to amend 21 CFR 1308.14(c)(16), (31), and (53) to remove suvorexant, lemborexant, and daridorexant from control under the CSA. DEA received a letter of intent dated May 19, 2023, from Eisai Inc, the manufacturer of lemborexant, in favor of the petition. DEA denied the petition in a letter dated [DATE TO BE ADDED].

a recommendation from the Assistant Secretary for Health (Assistant Secretary) of HHS and an evaluation of all relevant data by DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule V controlled substances on any person who handles or proposes to handle suvorexant, lemborexant, or daridorexant.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of DEA) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

Suvorexant, lemborexant, and daridorexant are active ingredients in drug products approved by the U.S. Food and Drug Administration (FDA) for the treatment of insomnia (Belsomra, Dayvigo, and Quviviq, respectively). Suvorexant, lemborexant, and daridorexant are orally active and belong to the dual orexin receptor antagonists (DORA) class of substances. All three substances inhibit orexin 1 (OX1) and orexin 2 (OX2) receptors. DEA placed these substances in schedule IV of the CSA based on HHS' evaluation and recommendations and concurrence by the National Institute of Drug Abuse (NIDA) asserting that the abuse liability studies in humans showed the DORAs produce reinforcing effects and have a potential for abuse that is similar to that of schedule IV substances, such as zolpidem.[6]

Proposed Determination to Transfer Suvorexant, Lemborexant, and Daridorexant from Schedule IV to Schedule V

[6] *Schedules of Controlled Substances; Placement of Daridorexant into Schedule IV*, 87 FR 59296 (Sept. 30, 2022); *Schedules of Controlled Substances; Placement of Lemborexant into Schedule IV*, 86 FR 12257 (Mar. 3, 2021); *Schedules of Controlled Substances; Placement of Suvorexant into Schedule IV*, 79 FR 51243 (Aug. 28, 2014).

In accordance with 21 U.S.C. 811(b), DEA gathered the necessary data and, on February 14, 2024, submitted it to the then-Assistant Secretary for Health of HHS with a request for scientific and medical evaluation and scheduling determination for the three DORAs.

On December 31, 2025, HHS provided DEA a scientific and medical evaluation entitled, "Basis for the recommendation that suvorexant, lemborexant, and daridorexant be controlled in schedule V under the Controlled Substances Act," and a scheduling recommendation. Following consideration of the eight factors and findings related to the substances' abuse potential, legitimate medical use, and dependence liability, HHS recommended that suvorexant, lemborexant, and daridorexant be transferred from schedule IV to schedule V of the CSA under 21 U.S.C. 812(b).

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, and all other relevant data, and completed its own eight-factor review document on suvorexant, lemborexant, and daridorexant pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in this proposal to transfer suvorexant, lemborexant, and daridorexant from schedule IV to schedule V of the CSA. Both DEA and HHS analyses are available in their entirety under "Supporting and Related Material" of the public docket for this rule at *https://www.regulations.gov* under docket number DEA-1645.

1. *Its Actual or Relative Potential for Abuse*

In addition to considering the information HHS provided in its scientific and medical evaluation document for suvorexant, lemborexant, and daridorexant, DEA also considered all other relevant data regarding actual or relative potential for abuse of suvorexant, lemborexant, and daridorexant. The term "abuse" is not defined in the CSA; however, the legislative history

of the CSA suggests the following four prongs in determining whether a particular drug or substances has a potential for abuse:[7]

> *a. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or*
>
> *b. There is a significant diversion of the drug or substance from legitimate drug channels; or*
>
> *c. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*
>
> *d. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.*

As HHS noted in their scientific and medical evaluation, there have been reports of adverse effects associated with the use of suvorexant, lemborexant, and daridorexant since their respective approvals in various databases, such as America's Poison Centers National Poison Data System (NPDS), the FDA Adverse Event Reporting System (FAERS), and National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance. Based on the available data, suvorexant had the most cases reported into NPDS and FEARS, 674 and 154, respectively. There were 217 cases that included lemborexant in NPDS and 15 in FAERS. As for daridorexant, the DORA with the least amount of marketed time, there have been 66 reports in NPDS and 35 in FAERS. Further, HHS identified 17 emergency department visits involving either suvorexant, lemborexant, or daridorexant.

FDA is not aware of any significant diversion from legitimate drug channels, including research activities or manufacturing facilities, for suvorexant, lemborexant, and daridorexant.

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[7] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

National Forensic Laboratory Information System (NFLIS-Drug) data reflects that suvorexant, lemborexant, and daridorexant are present on the United States drug market. From 2015 to December 2025, NFLIS-Drug registered 53, 1, and 1 report from 22 states pertaining to the trafficking, distribution, and potential abuse of suvorexant, lemborexant, and daridorexant, respectively.[8] These encounters of suvorexant, lemborexant, and daridorexant by law enforcement indicate that these substances are being trafficked and distributed in the United States. HHS also noted instances of individuals using their prescribed drug in ways not prescribed by their healthcare provider or using diverted prescription drugs on their own initiative.

As noted in the respective Final Rules for suvorexant, lemborexant, and daridorexant,[9] these substances are selective DORAs that are currently controlled in schedule IV of the CSA and are the only three substances with this exact mechanism of action. However, they do share characteristics with other controlled substances, such as zolpidem (schedule IV), a sedative-hypnotic drug. HHS noted that the traditional non-clinical abuse potential assessments showed limited or no signs of abuse potential of the DORAs as discussed further in Factors 2 and 7. However, data from human abuse potential (HAP) studies indicated similar subjective effects (e.g., "Overall Drug Liking," "Take Drug Again," and 'in the moment' ratings of "High and Good" and "Drug Liking") to substances currently in schedule IV of the CSA, such as zolpidem, and other positive controls in clinical trials.

In HHS's scientific and medical evaluation, it was noted that the DORAs have low market penetration for medical use. This makes the available evidence on scope, duration, and abuse limited, and limits the availability for diversion, abuse, or misuse by prescribed patients.

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[8] NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by Federal, state and local forensic laboratories in the United States. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77330, 77332 (Dec. 12, 2011). NFLIS-Drug data was queried on January 5, 2026; 2025 data is still reporting.

[9] *See supra* note 6.

As such, HHS also compared the abuse potential of the DORAs to triazolam (schedule IV), a substance that is used to treat insomnia and has similar medical utilization. Triazolam had similar abuse and misuse cases compared to the DORAs.

Overall, these data demonstrate there are instances of abuse, misuse, overdose, and potential diversion of suvorexant, lemborexant, and daridorexant that is contrary to medical advice. These substances are capable of creating hazards to the health of the user or to the safety of the community (*see* Factors 5 and 6). Taken together these factors suggest that abuse potential for the DORAs is more similar to other substances in schedule V.

2. *Scientific Evidence of its Pharmacological Effect, if Known*

The Notice of Proposed Rulemaking (NPRM) for suvorexant noted that the orexin signaling pathway was discovered in 1998 and has been associated with sleep and wakefulness, appetite, metabolism, stress response, reward/addiction, and analgesia.[10] Data regarding the pharmacological effects of the DORAs can be found in further detail in the NPRM or Interim Final Rule (IFR) for each of these substances and the scientific and medical evaluation conducted by HHS.[11] In brief, the drug sponsors submitted *in vitro* binding study reports for suvorexant and lemborexant and functional study reports for all three substances for review as part of the New Drug Application (NDA) process. All three substances bind to and are antagonists at the OX1 and OX2 receptors, as previously reported. Non-clinical *in vivo* studies of suvorexant, lemborexant, and daridorexant showed limited indication of abuse potential. However, in HAP studies conducted by the respective sponsors during drug development, suvorexant, lemborexant, and daridorexant produced positive subjective effects that are indicative of abuse potential and similar to schedule IV substances, such as zolpidem. As for adverse events (AEs), somnolence was the most frequent AE, which is consistent with their

[10] *Schedules of Controlled Substances: Placement of Suvorexant into Schedule IV*, 79 FR 8639 (Feb. 13, 2014).
[11] *See id.*; *Schedules of Controlled Substances: Placement of Lemborexant in Schedule IV,* 85 FR 19387 (Apr. 7, 2020); *Schedules of Controlled Substances: Placement of Daridorexant in Schedule IV*, 87 FR 20313 (Apr. 7, 2022).

mechanism for treating insomnia. During the drug development clinical trials, abuse-related AEs were infrequent for these substances at therapeutic levels.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance*

As previously described in the previously published NPRM and IFRs, suvorexant, lemborexant, and daridorexant are primarily metabolized by the cytochrome P450 enzyme, CYP3A4. Suvorexant is metabolized into numerous metabolites, with one identified as the major circulating metabolite. Lemborexant and daridorexant are metabolized into three major metabolites. Forensic testing for the DORAs may be limited. Methods to detect and validate suvorexant using whole blood liquid chromatography-tandem mass spectrometry were published in April 2025. Method development and validation have not been published for lemborexant and daridorexant.

Suvorexant, lemborexant, and daridorexant have currently accepted medical use in treatment in the United States because they are FDA-approved for the treatment of insomnia. No additional assessments for determining whether a drug has a currently accepted medical use in treatment in the United States were conducted.

4. *Its History and Current Pattern of Abuse*

The DORAs, as a class, have low market penetration for medical use as prescription drugs. This limits the availability of drug supply that could lead to diversion for abuse purposes or abuse and misuse by patients prescribed these drug products. However, HHS provided new analyses of epidemiology data that are useful in assessing the historical and current patterns of abuse for suvorexant, lemborexant, and daridorexant compared to schedule IV drug comparators, such as temazepam, triazolam, and zolpidem. Temazepam, triazolam, and zolpidem are all approved by FDA for the treatment of insomnia and have depressive effects on the central nervous system (CNS), but through a different mechanism of action. According to HHS, the total number of prescriptions for the DORAs, as a class, increased 75 percent from 559,000 to 977,000, with fluctuation of each substance year over year. DORAs were utilized at a lower

estimated rate at of the total prescriptions, relative to schedule IV substances that have FDA-approval for the treatment of insomnia, including zolpidem and temazepam, but comparatively to triazolam.

NFLIS-Drug was queried on January 5, 2026, for the DORAs. From 2015 to 2025, the DORAs were encountered 55 times, with 53 reports including suvorexant, and 1 report of both lemborexant and daridorexant. Encounters of the DORAs were generally encountered alone and not in conjunction with other controlled substances. The DORAs have been encountered in 22 states. DEA notes that the encounter data of the DORAs may be underreported, due to limited availability of reference material and recency of detection methods.

5. *The Scope, Duration and Significance of Abuse*

As noted in Factor 4, the DORAs have low market penetration for medical use as prescription products, which limits both the data available to assess the full scope, duration, and significance of abuse as well as to the overall amount of substance that can be diverted. Additionally, as DEA noted in Factor 3, the validated detection method for suvorexant is a more recent development and likely contributes to underreporting data related to abuse.

Compared to zolpidem (schedule IV) and temazepam (schedule IV), the DORAs were associated with fewer numbers of abuse or misuse cases, but the number of cases was comparable as a class to those of triazolam (schedule IV). HHS stated the lower number of abuse or misuse cases relative to zolpidem and temazepam may be attributable, at least in part, to the lower medical utilization of these DORAs.

6. *What, if any, Risk There is to the Public Health*

Across multiple data sources, single-substances cases suggest suvorexant, lemborexant, and daridorexant were primarily misused to achieve a therapeutic hypnotic effect, with mostly minor adverse effects. Of note, the number of abuse or misuse cases captured in these surveillance databases involving the DORAs is low; lower than those of zolpidem (schedule IV) and temazepam (schedule IV), but similar to triazolam (schedule IV). This may be due to the

overall lower utilization of any of the DORAs relative to zolpidem and temazepam. The risks associated with abuse and misuse to the individual or others are likely underreported, including those relating to driving impairment, due to the recency of the publication of validated testing methods.

7. *Its Psychic or Physiological Dependence Liability*

HHS reviewed available physical and psychic dependence liability data in rodents and humans for suvorexant, lemborexant, and daridorexant from the respective study drug NDAs. The currently available nonclinical and clinical data suggest suvorexant, lemborexant, and daridorexant do not produce physical or psychological dependence. FDA noted this is in contrast with many drugs currently in schedule IV and V of the CSA.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA*

Suvorexant, lemborexant, and daridorexant are not known to be immediate precursors to any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion:

After considering the scientific and medical evaluation conducted by HHS, HHS's accompanying scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence that the potential for abuse of suvorexant, lemborexant, and daridorexant is similar to that of schedule IV substances; however, they do not produce physical or psychological dependence. As such, DEA hereby proposes to transfer these three substances from schedule IV to schedule V of the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule.[12] After consideration of the analysis and recommendation of the Assistant

[12] 21 U.S.C. 812(b).

Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. Suvorexant, Lemborexant, and Daridorexant Have a Low Potential for Abuse Relative to the Drugs or Other Substances in Schedule IV.

The dual orexin antagonists suvorexant, lemborexant, and daridorexant have prior FDA approval for treatment of insomnia and were placed in schedule IV. The preclinical abuse potential studies on these substances did not demonstrate a signal of abuse potential. However, data from HAP studies indicated similar subjective effects to substances currently in schedule IV of the CSA, such as zolpidem. Abuse cases involving suvorexant, lemborexant, and daridorexant were assessed based on the limited available epidemiological data compared to substances in schedule IV. The number of abuse cases are low, lower than those of zolpidem and temazepam (which have higher rates of prescriptions), yet relatively similar to abuse of triazolam.

2. Suvorexant, Lemborexant, and Daridorexant Have Currently Accepted Medical Use in Treatment in the United States.

Suvorexant, lemborexant, and daridorexant are legally marketed in the United States as active ingredients of Belsomra, Dayvigo, and Quviviq, respectively for the treatment of insomnia. Thus, suvorexant, lemborexant, and daridorexant have a currently accepted medical use in treatment in the United States.

3. Abuse of Suvorexant, Lemborexant, and Daridorexant May Lead to Limited Physical Dependence or Psychological Dependence Relative to the Drugs or Other Substances in Schedule IV.

The currently available nonclinical and clinical data suggest suvorexant, lemborexant, and daridorexant do not produce physical or psychological dependence. FDA noted this is in contrast with many drugs currently in schedule IV and V of the CSA.

Requirements for Handling Suvorexant, Lemborexant, and Daridorexant

Under the CSA, schedule IV and V controlled substances are subject to identical regulatory controls and administrative sanctions. If this rule is finalized as proposed, suvorexant, lemborexant, and daridorexant would be subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule V controlled substances. Because suvorexant, lemborexant, and daridorexant, are currently schedule IV substances, transferring these substances from schedule IV to schedule V would impose the same controls and sanctions as those that currently exist, 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) suvorexant, lemborexant, and daridorexant, or who desires to handle suvorexant, lemborexant, and daridorexant, would need to 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. These registration requirements, however, are not applicable to patients (ultimate users) who possess suvorexant, lemborexant, and daridorexant, pursuant to a lawful prescription.

2. *Disposal of stocks.* Any person unwilling or unable to maintain a DEA registration as of the effective date of a final scheduling action for suvorexant, lemborexant, and daridorexant would be required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security*. Suvorexant, lemborexant, and daridorexant would be subject to schedule V security requirements for DEA registrants and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71-1301.76. Non-practitioners handling suvorexant, lemborexant, and daridorexant would also need to comply with the employee screening requirements of 21 CFR 1301.90-1301.93. These requirements,

however, are not applicable to patients (ultimate users) who possess suvorexant, lemborexant, and daridorexant, pursuant to a lawful prescription.

4. *Labeling and Packaging*. All labels, labeling, and packaging for commercial containers of suvorexant, lemborexant, and daridorexant would need to comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory*. Every DEA registrant who possesses any quantity of suvorexant, lemborexant, and daridorexant on the effective date of a final scheduling action must still need to take inventories of suvorexant, lemborexant, and daridorexant pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.These requirements, however, are not applicable to patients (ultimate users) who possess suvorexant, lemborexant, and daridorexant, pursuant to a lawful prescription.

6. *Records and Reports*. Every DEA registrant would need to maintain records and submit reports with respect to suvorexant, lemborexant, and daridorexant pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1307, and 1312.

7. *Prescriptions.* All prescriptions for suvorexant, lemborexant, and daridorexant, or products containing suvorexant, lemborexant, and 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 V controlled substances, such registrants should be advised that (consistent with the foregoing considerations) any manufacturing or distribution of suvorexant, lemborexant, and daridorexant may only be for the legitimate purposes authorized by the Federal Food, Drug, and Cosmetic Act, as applicable, and the CSA.

9. *Importation and Exportation*. All importation and exportation of suvorexant, lemborexant, and daridorexant would need to 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 suvorexant, lemborexant, and daridorexant not authorized by, or in violation of, the CSA or its implementing regulations, would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, 14192, and 14294

In accordance with 21 U.S.C. 811(a), this proposed 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 criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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, Consultation and Coordination with Indian Tribal Governments

This proposed 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 Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. As stated above, rescheduling these substances from schedule IV to schedule V will not change regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of suvorexant, lemborexant, and daridorexant because the controls and sanctions are the same under both schedules. Accordingly, there would be no economic impact on any entity that handles these substances, including small entities. Because there is no economic impact, DEA projects that this rule will not result in a significant economic impact on a substantial number of small entities.

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 and certifies 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 proposed rule would not impose a new collection of information under the Paperwork Reduction Act of 1995.[13] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the

[13] 44 U.S.C. 3501–3521.

following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, and 1117-0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA proposes to amend 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), 956(b), unless otherwise noted.

2. In § 1308.14:

a. Remove and reserve paragraphs (c)(16), (c)(31), and (c)(53).

3. In § 1308.15:

a. Add new paragraphs (e)(8-10);

The additions to read as follows:

§ 1308.15 Schedule V.

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(e) * * *

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(8) Daridorexant ([(2*S*)-2-(5-chloro-4-methyl-1*H*-benzimidazol-2-yl)-2-methylpyrrolidin-1-yl]-[5-methoxy-2-(triazol-2-yl)phenyl]methanone)	2410
(9) Lemborexant ((1*R*,2*S*)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-*N*-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide)	2245

(10) Suvorexant ([(7*R*)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl]-[5-methyl-2-(triazol-2-yl)phenyl]methanone)	2223
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Signing Authority

This document of the Drug Enforcement Administration was signed on August 6, 2026, by DEA Administrator Terrance C. Cole. 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.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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