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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–381]

Schedules of Controlled Substances: Placement of Suvorexant into Schedule IV

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 [(7*R*)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2*H*-1,2,3-triazol-2-yl)phenyl]methanone (suvorexant), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess), or propose to handle suvorexant.

DATES: Effective date: [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *." The Attorney General has delegated this authority to the Administrator of the DEA, 28 CFR 0.100, who in turn has redelegated that authority to the Deputy Administrator of the DEA. 28 CFR part 0, appendix to subpart R.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of Health and Human Services (HHS);[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action imposes the regulatory controls and administrative, civil, and criminal sanctions of schedule IV controlled substances on persons who handle or propose to handle suvorexant.

Background

Suvorexant ([(7*R*)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2*H*-1,2,3-triazol-2-yl)phenyl]methanone), also known as MK–4305, is a new chemical entity developed for the treatment of insomnia. Suvorexant is a novel, first in class, orexin receptor antagonist with a mechanism of action distinct from any marketed drug. It acts via inhibition of the orexin 1 (OX1) and orexin 2 (OX2) receptors. In

[1] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations.

pharmacological activity studies, suvorexant functioned as an antagonist as demonstrated by its ability to block agonist-induced calcium (Ca^{2+}) release. The U.S. Food and Drug Administration (FDA) approved the new drug application for suvorexant on August 13, 2014.

DEA and HHS Eight Factor Analyses

On June 27, 2013, the HHS provided the DEA with a scientific and medical evaluation document prepared by the FDA entitled "Basis for the Recommendation to Place Suvorexant in Schedule IV of the Controlled Substances Act." After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that suvorexant be controlled in schedule IV of the CSA under 21 U.S.C. 812(b). In response, the DEA conducted its own eight-factor analysis of suvorexant pursuant to 21 U.S.C. 811 (c). Both the DEA and HHS analyses are available in their entirety in the public docket for this rule (Docket Number DEA–381) at *http://www.regulations.gov* under "Supporting and Related Material."

Determination to Schedule Suvorexant

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from the HHS, the Deputy Administrator of the DEA published in the *Federal Register* a notice of proposed rulemaking (NPRM) entitled "Schedules of Controlled Substances: Placement of Suvorexant into Schedule IV" which proposed placement of suvorexant in schedule IV of the CSA. 79 FR 8639, Feb. 13, 2014. The proposed rule provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations by March 17, 2014. No requests for

such a hearing were received by the DEA. The NPRM also provided an opportunity for interested persons to submit written comments on the proposal on or before March 17, 2014.

Comments Received

The DEA received five comments on the proposed rule to schedule suvorexant. Two commenters supported controlling suvorexant as a schedule IV controlled substance. One commenter opposed the control of suvorexant, one commenter did not articulate an official position, and one commenter was in favor of controlling suvorexant as a schedule III controlled substance, rather than a schedule IV controlled substance.

Support for the Proposed Rule:

Two commenters supported controlling suvorexant as a schedule IV controlled substance. These commenters indicated support for controlling suvorexant under the CSA based on the abuse potential of the substance. The commenters noted that controlling suvorexant as a schedule IV controlled substance is appropriate because it is similar to zolpidem (schedule IV), while one commenter stated that suvorexant produces fewer adverse effects than zolpidem. The commenters believe that controlling suvorexant as a schedule IV controlled substance will provide the necessary controls to prevent its diversion.

DEA Response: The DEA appreciates the comments in support of this rulemaking.

Opposition to the Proposed Rule:

Two commenters opposed the proposal to control suvorexant as a schedule IV controlled substance, and one commenter did not articulate an official position but expressed concern about the side effects of suvorexant.

Request Not to Control Suvorexant:

One commenter opposed controlling suvorexant because they believed that there was a lack of strong scientific evidence that suvorexant has been abused, and the comparison of suvorexant with zolpidem (schedule IV) is incorrect due to each compound eliciting its effects via different mechanisms of action. The commenter was also concerned that controlling suvorexant will make it more difficult for patients to obtain the substance once it is approved by the FDA.

DEA Response: The DEA does not agree. Suvorexant is a novel, first in class, new chemical substance and information on actual abuse data is not currently available. The legislative history of the CSA addresses the assessment of a new drug's potential for abuse,[2] and data from clinical studies investigating the abuse potential for suvorexant suggests that its effect is similar to zolpidem (schedule IV). Similarly, while the mechanism of action for suvorexant is distinct from any currently marketed drug for insomnia, human abuse potential studies demonstrated that suvorexant produced effects that were indistinguishable from zolpidem (schedule IV).

Burdens associated with acquiring a substance as a result of control under the CSA are not relevant factors to the determination whether a substance should be controlled or under what schedule a substance should be placed if it is controlled. *See* 21 U.S.C. 811 and 812. Nonetheless, the DEA disagrees with the unsupported statement that making

[2] The legislative history of the CSA provides that a substance may have a potential for abuse if: "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." Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444 (1970); as reprinted in 1970 U.S.C.C.A.N. 4566, 4601.

suvorexant a controlled substance will make it difficult for ultimate users to legally acquire the substance once it is approved by the FDA. If a DEA-registered practitioner lawfully prescribes suvorexant to treat a medical condition, it may be dispensed on the basis of an oral or written prescription. 21 CFR 1306.04(a), 1306.21.

Request to Control Suvorexant as a Schedule III Substance:

One commenter had multiple concerns regarding the placement of suvorexant in schedule IV. The commenter believed that further studies on minimal levels of effective suvorexant doses should be conducted to reduce the risks of driving accidents. The commenter also expressed concern about the FDA's statement that while effective, suvorexant is unsafe at various doses. This commenter believed that due to lack of conclusive findings, suvorexant should be categorized as a schedule III controlled substance for "safety and precautionary purposes" since it is a novel, first in class, new substance.

Another commenter, who did not articulate a specific position, expressed concern that the side effects produced by suvorexant were similar to the effects of sleep deprivation, including cognitive and psychomotor impairment.

DEA Response: The concerns about the limited research on minimal levels of effective suvorexant doses and the side effects of suvorexant and sleep deprivation, along with the statement that suvorexant is unsafe at various doses, are outside the scope of the DEA's scheduling authority. As part of the new drug approval process, the HHS provides scientific and medical evaluations of a drug or other substance to ensure that it is safe and effective for its intended use. This process is completely separate from the DEA's proceedings to control such drug or other substance. 21 U.S.C. 811.

The DEA does not agree that suvorexant should be controlled as a schedule III controlled substance. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *." This scheduling action was initiated when the DEA received a scientific and medical evaluation and a scheduling recommendation to control suvorexant as a schedule IV controlled substance from the Assistant Secretary of the HHS. In accordance with 21 U.S.C. 811(c), the DEA conducted its own analysis of the eight factors determinative of control or removal: (1) its actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significant of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The summary of each factor as analyzed by the DEA and the HHS, and as considered by the DEA in this scheduling action, was provided in the proposed rule. Both the DEA and the HHS analyses have been made available in their entirety under ''Supporting and Related Material'' of the public docket for this rule at *http://www.regulations.gov* under Docket Number DEA–381.

There is evidence that suvorexant has a potential for abuse comparable to zolpidem (schedule IV), and like zolpidem, suvorexant has a low potential for abuse relative to the

drugs or other substances in schedule III. Suvorexant was compared to zolpidem in human studies of recreational sedative users to measure its abuse potential relative to that of a sedative-hypnotic in schedule IV. The abuse potential of suvorexant (40, 80 and 150 mg) relative to zolpidem (15 and 30 mg) and placebo was evaluated via a visual analog scale VAS, with results demonstrating that the effects of suvorexant were statistically indistinguishable from zolpidem. The results of the human abuse potential study suggest that suvorexant and zolpidem produce similar reinforcing effects and have a similar potential for abuse. In addition, preclinical studies demonstrated that suvorexant (10, 20, 30 and 60 mg/kg) dose dependently reduced locomotor activity in rats, similar to other sedative drugs including zolpidem (schedule IV). Based on the review of the HHS evaluation and scheduling recommendation and all other relevant data, the DEA found that suvorexant has an abuse potential similar to other schedule IV drugs, including zolpidem (schedule IV).

Scheduling Conclusion

Based on consideration of all comments, the scientific and medical evaluation and accompanying recommendation of the HHS, and the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of potential for abuse of suvorexant. As such, the DEA is scheduling suvorexant as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA outlines the findings required for placing a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the

analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Deputy Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

(1) [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone (suvorexant) has a low potential for abuse relative to the drugs or other substances in schedule III. The overall abuse potential of suvorexant is comparable to the schedule IV controlled substance zolpidem;

(2) [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone (suvorexant) has a currently accepted medical use in treatment in the United States. Suvorexant was approved for marketing by FDA as a treatment for insomnia; and

(3) Abuse of [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone (suvorexant) may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. The potential for psychological dependence is similar to that of zolpidem (schedule IV).

Based on these findings, the Deputy Administrator of the DEA concludes that suvorexant, including its salts, isomers, and salts of isomers, warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Suvorexant

Upon the effective date of this final rule, any person who handles suvorexant is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing,

exporting, engagement in research, and conduct of instructional activities, of schedule IV controlled substances including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) suvorexant, or who desires to handle suvorexant, must be registered with the 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 as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any person who currently handles suvorexant and is not registered with the DEA must submit an application for registration and may not continue to handle suvorexant as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] unless the 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.

Security. Suvorexant is subject to schedule III–V security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b) and in accordance with 21 CFR 1301.71–1301.93, as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Labeling and Packaging. All labels, labeling, and packaging for commercial containers of suvorexant must comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302, as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Inventory. Every DEA registrant who possesses any quantity of suvorexant on the effective date of this final rule must take an inventory of all stocks of suvorexant on hand

as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER], pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with the DEA after [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] must take an initial inventory of all stocks of controlled substances (including suvorexant) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including suvorexant) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records. All DEA registrants must maintain records with respect to suvorexant pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1307, and 1312, as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Prescriptions. All prescriptions for suvorexant or products containing suvorexant must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Importation and Exportation. All importation and exportation of suvorexant must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and be in accordance with 21 CFR

part 1312 as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Liability. Any activity involving suvorexant not authorized by, or in violation of, the CSA, occurring as of [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] is unlawful, and may subject the person to administrative, civil, and/or criminal proceedings.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States,

on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

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

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this final rule is to place suvorexant, including its salts, isomers, and salts of isomers, into schedule IV of the CSA. No less restrictive measures (i.e., non-control, or control in schedule V) enable the DEA to meet its statutory obligations under the CSA. In preparing this certification, the DEA has assessed economic impact by size category and has considered costs with respect to the various DEA registrant business activity classes.

Suvorexant is a new molecular entity which has not yet been marketed in the United States or any other country. Accordingly, the number of currently identifiable manufacturers, importers, and distributors for suvorexant is extremely small. The publicly available materials also specify the readily identifiable persons subject to direct regulation by this final rule. Based on guidelines utilized by the Small Business

Administration (SBA), the suvorexant manufacturer/distributor/importer was determined not to be a small entity. Once generic equivalents of suvorexant are developed and approved for manufacturing and marketing, there may be additional manufacturers, importers, and distributors of suvorexant, but whether they may qualify as small entities cannot be determined at this time.

There are approximately 1.5 million controlled substance registrations that represent approximately 381,000 entities (which include businesses, organizations, and governmental jurisdictions). The DEA estimates that 371,000 (97%) of these entities are considered "small entities" in accordance with the RFA and SBA size standards. 5 U.S.C. 601(6); 15 U.S.C. 632. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the dispensing rates of new molecular entities, the DEA is unable to determine what number of these 371,000 small entities might handle suvorexant.

Despite the fact that the number of small entities possibly impacted by this rule could not be determined, the DEA concludes that they would not experience a significant economic impact as a result of this final rule. The DEA estimates all anticipated suvorexant handlers to be DEA registrants and currently 98% of DEA registrants (most of which are small entities) are authorized to handle schedule IV controlled substances. Registrants that handle suvorexant are expected to incur nominal additional security, inventory, and recordkeeping costs. These registered entities are likely to have already established and implemented the systems and processes required to handle schedule IV controlled substances and can easily absorb the costs of handling suvorexant with nominal to no additional economic burden. For example, because DEA–registered

pharmacies and institutional practitioners are likely to already be schedule IV handlers, they may secure schedule II–V controlled substances by dispersing such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. Additionally, because other DEA registrants who will handle suvorexant are likely to already be schedule IV handlers, they already should have existing secure storage areas for schedule II–V controlled substances, which we assume would be able to accommodate any new stocks of suvorexant. *See* 21 CFR 1301.75(b), 1301.72(b). Accordingly, the requirement to secure all controlled substances containing suvorexant would not impose a significant economic burden upon DEA-registered practitioners as the infrastructure and materials for doing so are already in place. The DEA therefore assumes that the cost of compliance with 21 CFR 1301.71–1301.77 as a result of this final rule is nominal.

Correspondingly, because DEA-registered manufacturers, distributors, and importers must label and package all schedule II-V controlled substances in accordance with 21 CFR part 1302, the requirement to label and package all controlled substances containing suvorexant in accordance with 21 CFR part 1302 would not impose a significant economic burden upon DEA-registered manufacturers, distributors, and importers as the infrastructure and materials for doing so would already be in place. Accordingly, compliance with 21 CFR part 1302 would not require significant additional manpower, capital investment, or recordkeeping burdens.

Because of these facts, this final 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.*), the DEA has determined and certifies pursuant to UMRA 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 for inflation) in any one year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of 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. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

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 (CRA)). This rule will not result in: an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic

and export markets. However, pursuant to the CRA, the DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, the DEA 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. Amend §1308.14 by redesignating paragraphs (c)(49) through (c)(54) as (c)(50) through (c)(55) and adding new paragraph (c)(49) to read as follows:

§ 1308.14 Schedule IV.

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(c) * * *

(49) Suvorexant……..……..... 2223

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Dated: August 21, 2014

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2014-20515 Filed 08/27/2014 at 8:45 am; Publication Date: 08/28/2014]