a main polymer, currently manufactured on an industrial scale for textile and other purposes, together with the distinguishing attributes that characterize them.

This ISO standard is reasonably available to interested parties. Members of the public can obtain copies of ISO 2076:2013(E) from the International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401–1214 Vernier, Geneva, Switzerland; (+41 22 749 01 11); *central@iso.org; https://www.iso.org/home.html.* They can also obtain copies from the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; (212) 642–4900; *isot@ansi.org; https://www.ansi.org.* This ISO standard is also available for inspection at the FTC Library, (202) 326–2395, Federal Trade Commission, Room H–630, 600 Pennsylvania Avenue NW, Washington, DC 20580.

List of Subjects in 16 CFR Part 303

Advertising, Incorporation by reference, Labeling, Recordkeeping, Textile fiber products.

For the reasons discussed in the preamble, the Commission amends part 303 of title 16, Code of Federal Regulations, as follows:

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

■ 1. The authority citation for part 303 continues to read as follows:

Authority: 15 U.S.C. 70 *et seq.*

■ 2. Amend § 303.7:
■ a. By revising the introductory text; and
■ b. In paragraph (v), by removing the words ''16 CFR 303.7(c)'' and adding, their place, the words ''paragraph (c) of this section''.

The revision reads as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

Pursuant to the provisions of section 7(c) of the Act, the Commission hereby establishes the generic names for manufactured fibers, together with their respective definitions, set forth in this section, and the generic names for manufactured fibers, together with their respective definitions, set forth in International Organization for Standardization (ISO) 2076:2013(E). ISO 2076:2013(E), ''Textiles—Man-made fibres—Generic names,'' Sixth edition, November 15, 2013, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51.

To enforce any edition other than that specified in this section, the Federal Trade Commission must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the Federal Trade Commission, 600 Pennsylvania Avenue NW, Room H–630, Washington, DC 20580, (202) 326–2222, and is available from: (a) The International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401–1214 Vernier, Geneva, Switzerland; (+41 22 749 01 11); *central@iso.org; https://www.iso.org/home.html;* and (b) the American National Standards Institute, 25 West 43rd Street, Fourth Floor, New York, NY 10036–7417; (212) 642–4900; *isot@ansi.org; https://www.ansi.org.* It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

* * * * *

By direction of the Commission, Commissioner Slaughter not participating.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–19515 Filed 10–5–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–658]

Schedules of Controlled Substances: Placement of Remimazolam in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On July 2, 2020, the U.S. Food and Drug Administration approved a new drug application for BYFAVO (remimazolam) for intravenous use. Remimazolam is chemically known as 4*H*-imidazol[1,2-*a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place remimazolam and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing remimazolam, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

DATES: The effective date of this rulemaking is October 6, 2020. Interested persons may file written comments on this rulemaking in accordance with 21 U.S.C. 811(j)(3) and 21CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before November 5, 2020. 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.

Interested persons may file a request for hearing or waiver of hearing in accordance with 21 U.S.C. 811(j)(3) and 21 CFR 1308.44. Requests for 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 on or before November 5, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–658'' on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://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 for your comment. Please be aware that submitted comments are not instantaneously available for public view on *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.
- *Paper comments:* Paper comments that duplicate the electronic submission 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, VA 22152.

• *Hearing requests:* All requests for hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 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: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted. If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information, including the complete Department of Health and Human Services (HHS) and DEA eight-factor analyses, to this interim final rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

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), 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the person's interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

All requests for a hearing and waivers of participation must be sent to DEA using the address information provided above.

Background and Legal Authority

Under the CSA, as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (section 2(b) of Pub. L. 114–89), DEA is required to commence an expedited scheduling action with respect to certain new drugs approved by the Food and Drug Administration (FDA). As provided in 21 U.S.C. 811(j), this expedited scheduling is required where both of the following conditions apply: (1) The Secretary of HHS has advised DEA that a New Drug Application (NDA) has been submitted for a drug that has a stimulant, depressant, or hallucinogenic effect on the central nervous system (CNS), and that it appears that such drug has an abuse potential; and (2) the Secretary of HHS recommends that DEA control the drug in schedule II, III, IV, or V pursuant to 21 U.S.C. 811(a) and (b). In these circumstances, DEA is required to issue an interim final rule controlling the drug within 90 days.

Subsection (j)(2) states that the 90-day timeframe starts the later of (1) the date DEA receives HHS' scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Subsection (j)(3) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause therefore. Thus, the purpose of subsection (j) is to speed the process by which DEA schedules newly approved drugs that are currently either in schedule I or not controlled (but which have sufficient abuse potential to warrant control) so that such drugs may be marketed without undue delay following FDA approval.[1]

Subsection (j)(3) further provides that the interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, DEA must issue a final rule in accordance with the scheduling criteria of 21 U.S.C. 811(b) through (d) and 812(b).

Remimazolam (4*H*-imidazol[1,2-*a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) or methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid), is a new molecular entity with CNS depressant properties. Remimazolam is an agonist at gamma-aminobutyric acid subtype A ($GABA_A$) receptors. On April 5, 2019, Cosmo Technologies, Ltd. (Sponsor) submitted an NDA for BYFAVO (remimazolam) to FDA with a proposed dose of 5.0 mg (intravenous; i.v.) with supplemental doses of 2.6 mg (i.v.). On July 2, 2020, DEA received notification that FDA, on the same date, approved the NDA for BYFAVO (remimazolam), under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), to be used as an i.v. treatment for the induction and maintenance of

[1] Given the parameters of subsection (j), in DEA's view, it would not apply to a reformulation of a drug containing a substance currently in schedules II through V for which an NDA has recently been approved.

procedural sedation in adults undergoing procedures lasting 30 minutes or less. In January 2020, remimazolam was approved for marketing in Japan for general anesthesia.[2]

Determination To Schedule Remimazolam

On July 10, 2020, DEA received from HHS a scientific and medical evaluation (dated April 15, 2020) entitled ''Basis for the Recommendation to Control Remimazolam and its Salts in Schedule IV of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of remimazolam, along with HHS's recommendation to control remimazolam and its salts under schedule IV of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that remimazolam meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS' recommendation, NDA approval by HHS/FDA, and DEA's determination, DEA is issuing this interim final rule to schedule remimazolam as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' in the public docket for this interim final rule at *http://www.regulations.gov,* under Docket Number ''DEA–658.'' Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

Remimazolam is a new molecular entity that has not been marketed in the United States, and was approved in Japan for general anesthesia in January 2020. Evidence regarding its diversion, illicit manufacturing, or deliberate ingestions is lacking. DEA notes that there are no reports for remimazolam in the National Forensic Laboratory Information System (NFLIS),[3] which collects drug cases submitted to and analyzed by state and local forensic laboratories. There were also no reports in STARLiMS,[4] DEA's laboratory drug evidence data system of record.

As stated by HHS, remimazolam is so related in action to depressant drugs such as benzodiazepines in schedule IV that it is reasonable to assume that there may be comparable diversions from legitimate channels, use contrary to or without medical advice, and capability of creating hazards to the users and to the safety of the community. Preclinical and clinical studies show that remimazolam has similar pharmacological mechanism of action as an agonist at the $GABA_A$ receptors as midazolam. Data gathered from general behavior studies indicate remimazolam produces a sedative effect, and similar abuse-related effects in humans and in animal studies to those of midazolam, a schedule IV depressant. It is likely that remimazolam has similar abuse potential and is likely to be abused for its depressant effects, contrary to medical advice.

2. Scientific Evidence of Its Pharmacological Effects, if Known

Remimazolam shares similar pharmacological mechanism of action via $GABA_A$ receptor agonism as schedule IV benzodiazepines, such as midazolam. The $GABA_A$ receptor is a ligand-gated chloride ion channel consisting of five subunits and a central chloride channel. Benzodiazepines enhance the opening of the ligand-gated chloride channel and the influx of chloride.

Remimazolam, similar to schedule IV benzodiazepines, has sedative activity in animals. Acute administration of remimazolam in rats elicited dose-dependent behaviors indicative of sedative and muscle relaxation properties of the drug. In a drug discrimination study using male rats previously trained to discriminate midazolam, remimazolam produced interoceptive cues that are similar to those of midazolam. Remimazolam was self-administered variably based on session duration. In the shorter-access paradigm (two-hour sessions), only two of four monkeys tested self-administered remimazolam, whereas for the longer-access paradigm (24-hour sessions), all four monkeys self-administered remimazolam at a rate higher than placebo and pentobarbital, the reference drug (a schedule II or III depressant).[5]

In human abuse potential studies, remimazolam, in agreement with its mechanism of action as a $GABA_A$ receptor agonist, produced subjective responses and abuse-related neuropharmacology profile similar to that of midazolam, a schedule IV depressant.

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

Remimazolam is a new molecular entity. It is chemically known as 4*H*-imidazol[1,2- *a*][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4*S*)-methyl ester, benzenesulfonate (1:1) and also as methyl 3-[(4*S*)-8-bromo-1-methyl-6-pyridin-2-yl-4*H*-imidazo[1,2-*a*][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid. It is a white to off-white powder that is freely soluble in water. In preclinical studies, remimazolam, an ester based drug, is rapidly hydrolyzed by tissue esterases, primarily in the liver by carboxylesterase-1, and results in one inactive metabolite. In humans, acute administration of the proposed therapeutic dose (5 mg, i.v.) of remimazolam resulted in rapid onset sedative effects (one to three minutes), fast time to maximal plasma concentration ($T_{max,}$ nine minutes), and a short half-life (twenty minutes).

4. Its History and Current Pattern of Abuse

There is no information on the history and current pattern of abuse for

[2] Keam SJ (2020). Remimazolam: First Approval. Drugs; 80(6):625–633.

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, Dec. 12, 2011. NFLIS data were queried April 23, 2020.

[4] On October 1, 2014, DEA implemented STARLiMS (a web-based, commercial laboratory information management system) to replace the System to Retrieve Information from Drug Evidence (STRIDE) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS. STARLiMS data were queried May 5, 2020.

[5] The HHS review of remimazolam incorrectly stated that pentobarbital was a schedule IV substance. FDA/Controlled Substance Staff through an email correspondence confirmed that it was an inadvertent error in the HHS review. Pentobarbital is currently controlled as schedule II (21 CFR 1308.12(e)), or as schedule III if any material, compound, mixture, or preparation containing any quantity of pentobarbital having a depressant effect on the central nervous system (21 CFR 1308.13(c)(1)), or any suppository dosage form and its salts that are approved by FDA for marketing only as a suppository (21 CFR 1308.13(c)(2)).

remimazolam, since it has not been marketed, legally or illegally, in the United States, and only recently in Japan. HHS notes that the abuse potential of remimazolam is similar to that of schedule IV benzodiazepines. Therefore, if remimazolam were available for marketing, it is likely to be abused in a manner similar to schedule IV benzodiazepines, such as midazolam.

DEA conducted a search of NFLIS and STARLiMS databases for remimazolam encounters. No records of encounters by law enforcement were identified in these databases, which is consistent with the fact that remimazolam is a new molecular entity.

The pharmacological mechanism of action of remimazolam through $GABA_A$ receptor agonism suggests that its pattern of abuse would be similar to schedule IV depressants with a similar mechanism of action, such as midazolam.

5. The Scope, Duration, and Significance of Abuse

Remimazolam is not marketed in the United States, legally or illegally, and marketed only recently in Japan. However, because of remimazolam's pharmacological similarities to schedule IV benzodiazepines, remimazolam, similar to these schedule IV substances, is likely to be abused when available in the market.

6. What, If Any, Risk There Is To the Public Health

According to HHS, the public health risk associated with remimazolam is due to its abuse potential and is largely borne by the individual. Data from preclinical and clinical studies showed that remimazolam has abuse potential similar to that of the schedule IV depressant midazolam. In clinical studies when remimazolam was given to healthy individuals, adverse events such as euphoric mood and somnolence occurred; thus, remimazolam produced rewarding and depressant effects, as would be expected from a benzodiazepine. Therefore, upon availability for marketing, it is likely to pose a public health risk to a degree similar to schedule IV benzodiazepines, such as midazolam.

7. Its Psychic or Physiological Dependence Liability

As described in the HHS review, the Sponsor conducted a study related to physical dependence liability produced by remimazolam in six cynomolgus monkeys (0.5, 0.75, and 1.0 mg/kg/h, continuous i.v. infusion for 28 days) and psychic dependence liability in 39 humans (doses tested 5 and 10 mg, i.v.).

During extended daily dosing administrations lasting a period of 28 days, all monkeys showed depressant signs, such as ataxia, slowed motion, and hyporeactivity. During the discontinuation phase, all monkeys showed withdrawal signs including: Facial apprehension, hyperirritability, piloerection, muscle rigidity, retching and vomiting, tremors, restlessness, and impaired motor activity. Decreases in food consumption and body weights were also observed. Severe withdrawal symptoms such as dissociation from the environment, systemic convulsions, and continuously prone position for 25 hours were observed in one monkey, and remimazolam administration lessened this withdrawal syndrome in this monkey. HHS concluded that remimazolam produces physical dependence, as evidenced by the withdrawal syndrome observed after its chronic administration was discontinued.

Remimazolam produced positive subjective responses to ratings of Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again in a human abuse potential study. The responses were significantly higher than the placebo and similar to midazolam, a schedule IV depressant. HHS concluded that remimazolam can produce psychic dependence to a similar extent as midazolam.

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

Remimazolam is not an immediate precursor of any controlled substance, as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's recommendation, and its own eight-factor analysis, DEA has determined that these facts and all relevant data constitute substantial evidence of potential for abuse of remimazolam. As such, DEA hereby schedules remimazolam as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

1. Remimazolam Has a Low Potential for Abuse Relative to the Drugs or Other Substances in Schedule III.

Remimazolam, similar to that of the schedule IV drug midazolam, is an agonist at $GABA_A$ receptors. Remimazolam produced depressant effects in general behavior assessments, and generalized to midazolam (schedule IV) in a drug discrimination study in animals, demonstrating it has $GABA_A$ receptor agonist properties. In a human abuse potential study, remimazolam at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again similar to those of midazolam (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that remimazolam produced abuse-related adverse events, namely euphoria and somnolence. Because remimazolam is similar to midazolam (schedule IV) in its abuse potential, remimazolam has a lower potential for abuse relative to the drugs or other substances in schedule III.

2. Remimazolam Has a Currently Accepted Medical Use in the United States.

FDA recently approved the NDA for BYFAVO (remimazolam) injection for use in the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. Thus, remimazolam has a currently accepted medical use for treatment in the United States.

3. Remimazolam May Lead To Limited Physical Dependence or Psychological Dependence Relative to the Drugs or Other Substances in Schedule III.

Remimazolam shares a similar pharmacology profile with benzodiazepine drugs. Abrupt discontinuation of benzodiazepines is associated with withdrawal symptoms. Remimazolam produced withdrawal symptoms after abrupt discontinuation in monkeys, indicative of physical dependence, similar to that of benzodiazepines. In addition, remimazolam produced positive subjective responses and euphoria-related adverse events in a human abuse potential study. It is likely that remimazolam can produce psychic dependence similar to midazolam. Thus, abuse of remimazolam may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III of the CSA.

Based on these findings, the Acting Administrator of DEA concludes that remimazolam warrants control in schedule IV of the CSA. 21 U.S.C. 812(b)(4).

Requirements for Handling Remimazolam

Remimazolam is subject to the CSA's schedule IV regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule IV substances, including the following:

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

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

3. *Security.* Remimazolam is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.77. Non-practitioners handling remimazolam must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of remimazolam must 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 remimazolam must take an inventory of remimazolam on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Any person who becomes registered with DEA to handle remimazolam must take an initial inventory of all stocks of controlled substances (including remimazolam) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

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

6. *Records and Reports.* DEA registrants must maintain records and submit reports for remimazolam, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317.

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

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

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

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

Regulatory Analyses

Administrative Procedure Act

Section 553 of the APA (5 U.S.C. 553) generally requires notice and comment for rulemakings. However, 21 U.S.C. 811(j) provides that in cases where a certain new drug is (1) approved by HHS, under section 505(c) of the FDCA and (2) HHS recommends control in CSA schedule II–V, DEA shall issue an interim final rule scheduling the drug within 90 days. As stated in the legal authority section, the 90-day time frame is the later of: (1) the date DEA receives HHS's scientific and medical evaluation/scheduling recommendation, or (2) the date DEA receives notice of the NDA approval by HHS. Additionally, subsection (j) specifies that the rulemaking shall become immediately effective as an interim final rule without requiring DEA to demonstrate good cause.

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

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

This interim final rule is not an E.O. 13771 regulatory action pursuant to E.O. 12866 and OMB guidance.[6]

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have

[6] Office of Mgmt. & Budget, Exec. Office of The President, Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 Titled ''Reducing Regulation and Controlling Regulatory Costs'' (Feb. 2, 2017).

substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA. Under 21 U.S.C. 811(j), DEA is not required to publish a general notice of proposed rulemaking. Consequently, the RFA does not apply to this interim final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. 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 the Congressional Review Act (CRA), 5 U.S.C. 804. 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, DEA has submitted a copy of this interim 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, 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), 956(b) unless otherwise noted.

■ 2. In § 1308.14:

■ a. Redesignate paragraphs (c)(51) through (c)(57) as (c)(52) through (c)(58); and

■ b. Add new paragraph (c)(51).

The addition reads as follows:

§ 1308.14 Schedule IV.

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(c) * * *

(51) Remimazolam	2846

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Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–19313 Filed 10–5–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 9924]

RIN 1545–B032

Income Tax Withholding From Wages

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document sets forth final regulations that provide guidance for employers concerning income tax withholding from employees' wages. These final regulations concern the amount of Federal income tax employers withhold from employees' wages, implement changes in the Internal Revenue Code made by the Tax Cuts and Jobs Act, and reflect the redesigned withholding allowance certificate (Form W–4) and related IRS publications. These final regulations affect employers that pay wages subject to Federal income tax withholding and employees who receive wages subject to Federal income tax withholding.

DATES:

Effective date: These final regulations are effective on October 6, 2020.

Applicability dates: For dates of applicability see §§ 31.3402(a)–1(h), 31.3402(b)–1(b), 31.3402(c)–1(f), 31.3402(f)(1)–1(c), 31.3402(f)(2)–1(h), 31.3402(f)(3)–1(d), 31.3402(f)(4)–1(e), 31.3402(f)(5)–1(d), 31.3402(f)(6)–1(c), 31.3402(g)–1(d), 31.3402(h)(4)–1(c), 31.3402(i)–1(b), 31.3402(l)–1(e), 31.3402(m)–1(f), and 31.3402(n)–1(f).

FOR FURTHER INFORMATION CONTACT: Concerning these final regulations, Mikhail Zhidkov of the Office of Associate Chief Counsel (Employee Benefits, Exempt Organizations, and Employment Taxes), (202) 317–4774 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 3402(a)(1) provides that, except as otherwise provided in section 3402, every employer making a payment of wages shall deduct and withhold from such wages a tax determined in accordance with tables or computational procedures prescribed by the Secretary of the Treasury. Section 3402(a)(1) further provides that any tables or procedures prescribed under section 3402(a)(1) shall be in such form, and provide for such amounts to be deducted and withheld, as the Secretary determines to be most appropriate to carry out the purposes of chapter 1 (imposition of individual income tax). Section 3402 sets forth certain methods of withholding but also gives the Secretary broad regulatory authority in providing for tables or computational procedures for income tax withholding.

Generally, employers apply the withholding tables or computational procedures based on the entries on the Form W–4 the employee furnishes the employer. An employee who receives wages subject to withholding under section 3402 is required to furnish his or her employer a Form W–4 on commencement of employment or, generally, within 10 days after the employee experiences a ''change of status'' that reduces the ''withholding allowance'' to which the employee is entitled. *See* section 3402(f)(2).

An employee completes Form W–4 based on the employee's personal tax situation by applying the factors listed in section 3402(f)(1). Section 3402(f)(1) describes the combination of these factors as the employee's ''withholding allowance.'' Once an employee completes a valid Form W–4, the employee must furnish the Form W–4 to the employer. The employer puts the Form W–4 into effect in accordance with the timing rules in section