various projects. A tool manufacturer sends the influencer an expensive full-size lathe in the hope that the influencer would post about it. The woodworker uses the lathe for several products and comments favorably about it in videos. If a significant minority of viewers are likely unaware that the influencer received the lathe free of charge, the woodworker should clearly and conspicuously disclose receiving it for free, a fact that could affect the credibility that viewers attach to the endorsements. The manufacturer should advise the woodworker at the time it provides the lathe that this connection should be disclosed, and it should have reasonable procedures in place to monitor the influencer's postings for compliance and follow those procedures. (*See* § 255.1(d).)

(8) *Example 8.* An online community has a section dedicated to discussions of robotic products. Community members ask and answer questions and otherwise exchange information and opinions about robotic products and developments. Unbeknownst to this community, an employee of a leading home robot manufacturer has been posting messages on the discussion board promoting the manufacturer's new product. Knowledge of this poster's employment likely would affect the weight or credibility of the endorsements. Therefore, the poster should clearly and conspicuously disclose their relationship to the manufacturer. To limit its own liability for such posts, the employer should engage in appropriate training of employees. To the extent that the employer has directed such endorsements or otherwise has reason to know about them, it should also be monitoring them and taking other steps to ensure compliance. (*See* § 255.1(d).) The disclosure requirements in this example would apply equally to employees posting their own reviews of the product on retail websites or review platforms.

(9) *Example 9.* A college student signs up to be part of a program in which points are awarded each time a participant posts on social media about a particular advertiser's products. Participants can then exchange their points for prizes, such as concert tickets or electronics. These incentives would materially affect the weight or credibility of the college student's endorsements. They should be clearly and conspicuously disclosed, and the advertiser should take steps to ensure that these disclosures are being provided.

(10) *Example 10.* Great Paper Company sells photocopy paper with packaging that has a seal of approval from the No Chlorine Products Association, a non-profit third-party association. Great Paper Company paid the No Chlorine Products Association a reasonable fee for the evaluation of its product and its manufacturing process. Consumers would reasonably expect that marketers have to pay for this kind of certification. Therefore, there is no unexpected material connection between the company and the association, and the use of the seal without disclosure of the fee paid to the association would not be deceptive.

(11) *Example 11.* A coffee lover creates a blog that reviews coffee makers. The blogger writes the content independently of the marketers of the coffee makers but includes affiliate links to websites on which consumers can buy these products from their marketers. Whenever a consumer clicks on such a link and buys the product, the blogger receives a portion of the sale. Because knowledge of this compensation could affect the weight or credibility site visitors give to the blogger's reviews, the reviews should clearly and conspicuously disclose the compensation.

(12) *Example 12.* (i) Near the beginning of a podcast, the host reads what is obviously a commercial for a product. Even without a statement identifying the advertiser as a sponsor, listeners would likely still expect that the podcaster was compensated, so there is no need for a disclosure of payment for the commercial. Depending upon the language of the commercial, however, the audience may believe that the host is expressing their own views in the commercial, in which case the host would need to hold the views expressed. (*See* § 255.0(b).)

(ii) Assume that the host also mentions the product in a social media post. The fact that the host did not have to make a disclosure in the podcast has no bearing on whether there has to be a disclosure in the social media post.

(13) *Example 13.* An app developer gives a consumer a game app to review. The consumer clearly and conspicuously discloses in the review that they were given the app, which normally costs 99 cents, for free. That disclosure suggests that the consumer did not receive anything else for the review. If the app developer also gave the consumer $50 for the review, the mere disclosure that the app was free would be inadequate.

(14) *Example 14.* Speed Ways, an internet Service Provider, advertises that it has the ''Fastest ISP Service'' as determined by the ''Data Speed Testing Company.'' If Speed Ways commissioned and paid for the analysis of its and competing services, it should clearly and conspicuously disclose its relationship to the testing company because the relationship would likely be material to consumers in evaluating the claim. If the ''Data Speed Testing Company'' is not a bona fide independent testing organization with expertise in judging ISP speeds or it did not conduct valid tests that supported the endorsement message, the endorsement would also be deceptive. (*See* § 255.3(c)(3))

§ 255.6 Endorsements directed to children.

Endorsements in advertisements addressed to children may be of special concern because of the character of the audience. Practices that would not ordinarily be questioned in advertisements addressed to adults might be questioned in such cases.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–14795 Filed 7–25–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–989]

Schedules of Controlled Substances: Temporary Placement of Etizolam, Flualprazolam, Clonazolam, Flubromazolam, and Diclazepam in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this temporary order to schedule five synthetic benzodiazepine substances: etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam, in schedule I of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of these five substances in schedule I is necessary to avoid imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed 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 these five specified controlled substances.

DATES: This temporary scheduling order is effective July 26, 2023, until July 26, 2025. If this order is extended or made permanent, DEA will publish a document in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) issues a temporary scheduling order [1] (in the form of a temporary amendment) to add the following five substances, including their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, to schedule I under the Controlled Substances Act (CSA):

- 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as etizolam),
- 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as flualprazolam),
- 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (commonly known as clonazolam),
- 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine (alternate chemical name: 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-[1,2,4]triazolo[4,3-*a*][1,4]benzodiazepine and commonly known as, flubromazolam), and
- 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one (commonly known as diclazepam).

Legal Authority

The CSA provides the Attorney General, as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100, with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b), if the Administrator finds that such action is necessary to avoid an imminent hazard to public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Administrator may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, and if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355. 21 U.S.C. 811(h)(1); 21 CFR part 1308.

Background

The CSA requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of an intent to place a substance in schedule I of the CSA temporarily (*i.e.,* to issue a temporary scheduling order). 21 U.S.C. 811(h)(4). The Administrator transmitted the required notice to the Assistant Secretary for Health of HHS (Assistant Secretary),[2] by letter dated October 27, 2021, regarding etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. The Assistant Secretary responded to this notice by letter dated January 3, 2022, and advised that, based on a review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications (INDs) or approved new drug applications (NDA) for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. The Assistant Secretary also stated that HHS had no objection to the temporary placement of these substances in schedule I.

DEA has taken into consideration the Assistant Secretary's comments as required by subsection 811(h)(4). DEA has found that the control of these five benzodiazepines in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam currently are not listed in any schedule under the CSA, and no exemptions or approvals under 21 U.S.C. 355 are in effect for these five benzodiazepine substances.

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NOI) to temporarily schedule etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam on December 23, 2022. 87 FR 78887. That NOI discussed findings from DEA's three-factor analysis dated October 2022, which DEA made available on *www.regulations.gov.*

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances. 21 U.S.C. 811(h)(3).

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1).

DEA's October 2022 three-factor analysis and the Assistant Secretary's January 3, 2022 letter are available in their entirety under the tab ''Supporting Documents'' of the public docket of this action at *www.regulations.gov.*

Five Benzodiazepine Substances: Etizolam, Flualprazolam, Clonazolam, Flubromazolam, and Diclazepam

The dramatic increase in trafficking and abuse associated with novel psychoactive substances (NPS) of the benzodiazepine class, also known as designer benzodiazepines, in the United States has become a national public health concern in recent years. The availability of NPS benzodiazepine substances in the illicit drug market continues to pose an imminent hazard to the public safety. The Centers for Disease Control and Prevention (CDC) highlights this issue in their Morbidity and Mortality Weekly Report (MMWR) published on August 27, 2021.[3] CDC indicated that from April 2019 to June 2020 prescription and illicit benzodiazepine-involved overdose deaths increased by 21.8 percent and 519.6 percent respectively. Additionally, benzodiazepines were involved in nearly 7,000 overdose

[1] Though DEA has used the term ''final order'' with respect to temporary scheduling orders in the past, this order adheres to the statutory language of 21 U.S.C. 811(h), which refers to a ''temporary scheduling order.'' No substantive change is intended.

[2] The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[3] Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report: Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines—38 States and the District of Columbia, 2019–2020. Vol. 70, No. 34. August 27, 2021.

deaths in 23 states from January 2019 to June 2020, accounting for 17 percent of all drug overdose deaths. Adverse health effects associated with the abuse of such substances, their continued evolution, and increased popularity of these substances have been a serious concern in recent years.

The increase in the co-use of opioids with designer benzodiazepines has become a particular concern as the United States continues to experience an unprecedented epidemic of opioid misuse and abuse.[4] CDC's 2021 MMWR further states that between January and June 2020, 92.7 percent of benzodiazepine-involved deaths also involved opioids and 66.7 percent involved illicitly manufactured fentanyl. The combination of benzodiazepines with opioids substantially enhances the potential for lethality. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are benzodiazepine substances recently identified on the illicit drug market in the United States.

The abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam has been associated with fatalities in recent years in the United States. The positive identification of these five substances in post-mortem cases is a serious concern to the public safety. Additionally, law enforcement data indicate that the substances at issue here have significant presence in the illicit drug market found in the United States. In light of the law enforcement encounters and fatalities associated with the abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam, these substances pose an imminent hazard to public safety.

Available data and information for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam, summarized below, indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision. DEA's three-factor analysis is available in its entirety under ''Supporting and Related Material'' of the public docket for this action at *www.regulations.gov* under Docket Number DEA–989.

Factor 4. History and Current Pattern of Abuse

The chemical synthesis of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam was previously reported in the scientific literature; however, the research did not lead to any medically approved products in the United States. Since 2012, synthetic drugs belonging to the benzodiazepine class have begun to emerge in the illicit drug market as evidenced by the identification of these drugs in forensic drug exhibits reported to the National Forensic Laboratory Information System (NFLIS-Drug)[5] and toxicology samples. Beginning in 2012, etizolam emerged on the illicit synthetic drug market as evidenced by its identification in drug seizures in the United States.

In recent years, there has been a rise in the recreational use of etizolam. As evidenced by their identification in NFLIS-Drug, diclazepam emerged in the United States' illicit drug market in 2014, flubromazolam and clonazolam in 2015, and flualprazolam in 2017. While these substances are not approved for medical use in the United States, etizolam is approved for medical use in Italy, India, and Japan.[6] In a letter dated January 3, 2022, the Assistant Secretary informed DEA that there are no INDs or FDA-approved NDAs for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in the United States. Hence, there are no legitimate channels for these substances as marketed drug products in the United States. These five benzodiazepine substances are likely to be abused in the same manner as other sedative hypnotics. They have been identified in tablet form, as white to beige powders, or in liquid forms, typically of unknown purity or concentration.

Based on data from NFLIS-Drug, law enforcement often encounters etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in counterfeit pills, liquid, or powder form. Substances often found in combination with some of these benzodiazepines include substances of abuse such as heroin (schedule I), fentanyl (schedule II), substances structurally related to fentanyl, other benzodiazepines (both FDA-approved schedule IV benzodiazepines and other novel non-controlled benzodiazepines), and tramadol (schedule IV). Evidence suggests that individuals are using these substances to obtain ''legal highs''[7] or to self-medicate. Information gathered from case histories and autopsy findings shows that deaths involving etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam were predominantly associated with poly-drug use.

Factor 5. Scope, Duration, and Significance of Abuse

Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are novel benzodiazepines and evidence suggests they are abused for their sedative effects (see Factor 6). In death investigations involving polysubstance use, the co-appearance of benzodiazepines and opioids in toxicological analysis was common. Between August 2019 and January 2020, flualprazolam and etizolam were identified in seven and six postmortem blood specimens, respectively, out of 18 deaths associated with the abuse of isotonitazene, a schedule I opioid that was recently controlled.[8] These cases corresponded to four states—Illinois (9), Indiana (7), Minnesota (1), and Wisconsin (1). Most (12) of the decedents were male. The ages ranged from 24 to 66 years old with an average age of 41 years.[9]

In another recent publication, 20 forensic postmortem cases were reviewed and analyzed for the presence of metonitazine, NPS benzodiazepines, and opioids. Clonazolam was positively identified in four cases, etizolam in two cases, flualprazolam in two cases, and

[4] Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report: Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines—38 States and the District of Columbia, 2019–2020. Vol. 70, No. 34. August 27, 2021.

[5] 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 comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1.0 million distinct annual state and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. 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* 76 FR 77330, 77332, Dec. 12, 2011.

[6] Although there is no evidence suggesting that etizolam, flualprazolam, clonazolam, flubromazolam, or diclazepam has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR 10499 (1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

[7] Substances used as ''legal highs'' are psychoactive substances that are not controlled under the CSA, but can be used to obtain a desired psychoactive effect.

[8] 85 FR 51342 and 86 FR 60761.

[9] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK. Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. Journal of Analytical Toxicology, 2020, 44(6):521–530.

pyrazolam in one case.[10] Law enforcement encounters of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam as reported to NFLIS-Drug include 34,781 drug reports since 2014 (queried 01/13/2022). NFLIS-Drug registered three encounters of etizolam in 2012 (first year of encounter) and 3,022 reports in 2021. Flualprazolam was first encountered in 2017 when one report was identified in NFLIS-Drug, and then in 2021, 1,305 encounters were reported. A similar trend was seen with clonazolam. During 2015 (its first year of encounter), 57 cases were reported in NFLIS-Drug, while 3,994 drug reports were identified in 2021. NFLIS-Drug registered five diclazepam encounters in 2014 (its first year of encounter) and 54 encounters in 2021. Flubromazolam encounters totaled 14 in 2015 (its first year of encounter) and 414 in 2021.

The population likely to abuse etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam appears to be the same as those abusing prescription benzodiazepines, barbiturates, and other sedative hypnotic substances. This is evidenced by drug user reports associated with these substances. Because abusers of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are likely to obtain these substances through unregulated sources, the identity, purity, and quantity of these substances are uncertain and inconsistent, thus posing significant adverse health risks to the end user.

The misuse and abuse of benzodiazepines have been demonstrated and are well-characterized.[11] According to the most recent data from the National Survey on Drug Use and Health (NSDUH),[12] as of 2020, an estimated 4.8 million people aged 12 years or older misused prescription benzodiazepines in the past year. This included 1.1 million young adults aged 18 to 25, 3.5 million adults aged 26 or older, and 157,000 adolescents aged 12 to 17. This population abusing prescription benzodiazepines is likely to be at risk of abusing etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. Individuals who initiate use of these five substances (*i.e.,* use a drug for the first time) are likely to be at risk of developing substance use disorder, overdose, and death at rates similar to that of other sedative hypnotics (*e.g.,* alprazolam, etc.). Law enforcement or toxicology reports demonstrate that the five substances at issue are being distributed and abused.

Factor 6. What, if Any, Risk There Is to the Public Health

The increase in benzodiazepine-related overdose deaths in the United States has been exacerbated recently by the availability of NPS benzodiazepines in the illicit drug market. Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam have been described as derivatives of other known benzodiazepines, each possessing various degrees of potency. Evidence suggests these substances are being abused for their sedative/hypnotic effects (see DEA 3-Factor Analysis). Public health risks associated with the five substances at issue here relate to their pharmacological similarities with known benzodiazepines. Thus, risk to the public health is associated with adverse reactions in humans, which are expected to include CNS depressant-like effects, such as slurred speech, ataxia, altered mental state, and respiratory depression.

Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam have been increasingly identified in toxicology reports, death investigations, and driving under the influence of drugs (DUID) cases since their first appearance in law enforcement seizures. According to the Center for Forensic Science Research and Education (CFSRE), a non-profit organization in collaboration with the Department of Justice and CDC between 2020 and 2021, etizolam was the most identified NPS benzodiazepine accounting for 697 total toxicology cases in 2020, many of which were co-identified with fentanyl. In 2021, etizolam was identified in 1,012 toxicology cases, while flualprazolam, clonazolam, flubromazolam, and diclazepam were associated with 432, 331, 170, and four toxicology cases, respectively (CSFRE Quarterly Trend Reports: NPS Benzodiazepines in the United States).

Death investigations associated with four of the five NPS benzodiazepines at issue here have increased in recent years. In a 2021 publication by the Orange County Crime Lab in Santa Ana, California, flualprazolam was identified as serving a contributory role in the death of 13 of 24 cases analyzed in the study.[13] In another recently published study, between August 2019 and January 2020, flualprazolam and etizolam were identified in seven and six postmortem blood specimens respectively, out of 18 deaths associated with the abuse of isotonitazene, a schedule I opioid.[14] Then, a study published in 2021 which compiled data from 254 reports published between 2008 and 2021, identified: 33 deaths associated with etizolam, 20 flualprazolam-related deaths, six emergency department (ED) visits associated with clonazolam, 14 flubromazolam-related ED visits, and one death, 12 DUID cases, and four ED visits associated with diclazepam.[15] Additionally, in 2020, the European Monitoring Centre for Drugs and Drug Addiction reported 34 deaths associated with diclazepam use, which were determined through the analysis of biological samples.[16] Furthermore, the National Poison Data System reported that between January 2014 and December 2017, clonazolam was the second most common benzodiazepine associated with poison control center calls, accounting for 50 incidents.[17]

Impaired driving is another risk factor associated with the use and abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam. In a recent published report from the

[10] Krotulski AJ, Papsun DM, Walton SE, and Logan BK. Metonitazene in the United States-Forensic toxicology assessment of a potent new synthetic opioid using liquid chromatography mass spectrometry. Drug Testing Analysis, 2021, 13(10):1697–1711.

[11] Votaw VR, Geyer R, Rieselbach MM, and McHugh RK. The epidemiology of benzodiazepine misuse: A systematic review. Drug Alcohol Dependence, 2019, 200:95–114.

[12] The National Survey on Drug Use and Health (NSDUH), formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The survey excludes homeless people who do not use shelters, active military personnel, and residents of institutional group quarters such as jails and hospitals. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (*i.e.,* ever used), past year, and past month abuse or dependence. The 2020 NSDUH annual report is available at *https://www.samhsa.gov/data/* (last accessed February 8, 2022).

[13] Ha HH and Mata DC. Flualprazolam distribution in postmortem samples. Journal of Forensic Sciences, 2022, 67(1): 297–308.

[14] Krotulski AJ, Papsun DM, Kacinko SL, and Logan BK. Isotonitazene Quantitation and Metabolite Discovery in Authentic Forensic Casework. Journal of Analytical Toxicology, 2020, 44(6): 521–530.

[15] Brunetti P, Giorgetti R, Tagliabracci A, Huestis MA, Busardò FP. Designer Benzodiazepines: A Review of Toxicology and Public Health Risks. Pharmaceuticals (Basel). 2021 Jun 11;14(6):560.

[16] EMCDDA (2020). EMCDDA response to WHO request for information on the new psychoactive substances, eutylone, α-PHiP, 4F-furanylfentanyl, 2-methyl-AP–237, and, diclazepam.

[17] Carpenter JE, Murray BP, Dunkley C, Kazzi ZN, Gittinger MH. Designer benzodiazepines: a report of exposures recorded in the National Poison Data System, 2014–2017. Clin Toxicol (Phila). 2019 Apr;57(4):282–286.

Sedgwick County Regional Forensic Science Center in Wichita, Kansas, 12 DUID case samples were analyzed. Etizolam was positively identified in three cases, while flubromazolam was identified in nine of these cases.[18] In a 2021 publication, similar involvement of flubromazolam in drug-impaired driving was reported in Canada where flubromazolam was detected in 10 percent of 113 case samples.[19] Diclazepam has also been implicated in DUID cases domestically and internationally. In a Norwegian study conducted between July 2013 and May 2016, diclazepam was identified in 15 of 77 analyzed samples taken from impaired drivers and individuals involved in other criminal offenses. Then, in 2019, a study of Norwegian drivers was conducted using 575 samples taken predominantly from intoxicated drivers and individuals who committed other criminal offenses.[20] Notably, 334 samples were found to contain diclazepam. Additionally, in a 2021 publication from Orange County Crime Laboratory in Santa Ana, California, researchers identified 22 samples that tested positive for flualprazolam in samples obtained from DUID investigations between August 2018 and September 2020.[21]

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and/or abuse of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam pose imminent hazards to public safety. DEA is not aware of any currently accepted medical uses for these substances in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam indicate that these five synthetic benzodiazepine substances have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision.

As required by 21 U.S.C. 811(h)(4), the Administrator transmitted to the Assistant Secretary for Health, via a letter dated October 27 2021, notice of her intent to place etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in schedule I on a temporary basis. HHS had no objection to the temporary placement of these substances in schedule I.

DEA subsequently published a NOI on December 23, 2022. 87 FR 78887.

Conclusion

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein set forth the grounds for her determination that it is necessary to temporarily place etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in schedule I of the CSA and finds that such placement is necessary to avoid an imminent hazard to the public safety.

This temporary order scheduling these substances will be effective on the date the order is published in the **Federal Register** and remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h)(1) and (2).

The CSA sets forth specific criteria for scheduling drugs or other substances. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done ''on the record after opportunity for a hearing'' conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with an appropriate process and the government any additional relevant information needed to make determinations. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this temporary order, etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, possession of, and engagement in research and conduct of instructional activities or chemical analysis with, schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with) or desires to handle, etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam 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, as of July 26, 2023. Any person who currently handles etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam and is not registered with DEA must submit an application for registration and may not continue to handle etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam as of July 26, 2023, 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. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA on or after July 26, 2023 is unlawful, and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is unable to obtain a schedule I registration to handle etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam must surrender all currently held quantities of these five substances.

3. *Security.* Etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam are subject to schedule I security requirements and must be handled in accordance with 21 CFR 1301.71–1301.93, as of July 26, 2023.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of etizolam, flualprazolam,

[18] Rohrig TP, Osawa KA, Baird TR, Youso KB. Driving Impairment Cases Involving Etizolam and Flubromazolam. J Anal Toxicol. 2021 Feb 6;45(1):93–98.

[19] Vaillancourt L, Viel E, Dombrowski C, Desharnais B, Mireault P. Drugs and driving prior to cannabis legalization: A 5-year review from DECP (DRE) cases in the province of Quebec, Canada. Accid Anal Prev. 2021 Jan;149:105832.

[20] Heide G, Høiseth G, Middelkoop G, and Øiestad ÅML. Blood concentrations of designer benzodiazepines: Relation to impairment and findings in forensic cases. Journal of Analytical Toxicology, 2020, 44(8): 905–914.

[21] Ha HH and Mata DC. Flualprazolam distribution in postmortem samples. Journal of Forensic Sciences, 2022, 67(1): 297–308.

clonazolam, flubromazolam, and diclazepam must comply with 21 U.S.C. 825 and 958(e) and 21 CFR part 1302. Current DEA registrants will have 30 calendar days from July 26, 2023 to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam on the effective date of this order must take an inventory of all stocks of these substances on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants will have 30 calendar days from the effective date of this order to comply with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam) on hand on a biennial basis pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle these five substances shall have 30 calendar days from the effective date of this order to comply with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of July 26, 2023. Manufacturers and distributors must also submit reports regarding these five substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* All DEA registrants who distribute etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of July 26, 2023.

9. *Importation and Exportation.* All importation and exportation of etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of July 26, 2023.

10. *Quota.* Only DEA-registered manufacturers may manufacture etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of July 26, 2023.

11. *Liability.* Any activity involving etizolam, flualprazolam, clonazolam, flubromazolam, and diclazepam not authorized by or in violation of the CSA, occurring as of July 26, 2023, is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

The CSA provides for expedited temporary scheduling actions where necessary to avoid imminent hazards to the public safety. Under 21 U.S.C. 811(h), the Administrator, as delegated by the Attorney General, may, by order, temporarily schedule substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) The publication of a notice in the **Federal Register** of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary for Health of HHS, as delegated by the Secretary of HHS. 21 U.S.C. 811(h)(1).

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the **Federal Register** a notice of intent, the notice-and-comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. The APA expressly differentiates between orders and rules, as it defines an ''order'' to mean a ''final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making.*'' 5 U.S.C. 551(6) (emphasis added). The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions, *see* 21 U.S.C. 811(a), it is noteworthy that, in section 811(h), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Alternatively, even if this action was subject to section 553 of the APA, the Administrator finds that there is good cause to forgo its notice-and-comment requirements, as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid imminent hazards to public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of section 553 of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Assistant Secretary in response to the notice that DEA transmitted to the Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a ''rule'' as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan

programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. Because this is not a rulemaking action, this is not a significant regulatory action as defined in section 3(f) of E.O. 12866.

This action will 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. Therefore, in accordance with E.O. 13132 (Federalism), it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Signing Authority

This document of the Drug Enforcement Administration was signed on July 18, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

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

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 part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraphs (h)(57) through (h)(61) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(57) 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: etizolam) 2780

(58) 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flualprazolam) 2785

(59) 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: clonazolam) 2786

(60) 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flubromazolam) 2788

(61) 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one, its salts, isomers, and salts of isomers (Other name: diclazepam) 2789

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–15748 Filed 7–25–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 9978]

RIN 1545–BQ08

Recapture of Certain Excess Employment Tax Credits Under COVID–19 Legislation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document sets forth the final regulations under sections 3111, 3131, 3132, 3134, and 3221 of the Internal Revenue Code (Code) issued under the authority granted by the Families First Coronavirus Response Act, the Coronavirus Aid, Relief, and Economic Security Act, and the American Rescue Plan Act of 2021. These final regulations authorize the assessment of any erroneous refund of the tax credits paid under sections 7001 and 7003 of the Families First Coronavirus Response Act (including any increases in those credits under section 7005 thereof), and section 2301 of the Coronavirus Aid, Relief, and Economic Security Act, as well as under sections 3131, 3132 (including any increases in those credits under section 3133), and 3134 of the Code.

DATES:

Effective date: These final regulations are effective on July 24, 2023.

Applicability date: For date of applicability, *see* §§ 31.3111–6(e), 31.3131–1(d), 31.3132–1(d), 31.3134–1(d), and 31.3221–5(e).

FOR FURTHER INFORMATION CONTACT: NaLee Park at 202–317–6798 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document sets forth amendments to the Employment Tax Regulations (26 CFR part 31) under sections 3111, 3131, 3132, 3133, 3134, and 3221.

The Families First Coronavirus Response Act (Families First Act), Public Law 116–127, 134 Stat. 178 (March 18, 2020), as amended and extended by the COVID-related Tax Relief Act of 2020 (Tax Relief Act), enacted as Subtitle B of Title II of Division N of the Consolidated Appropriations Act, 2021, Public Law 116–260, 134 Stat.1182 (December 27, 2020), and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, 134 Stat. 281 (March 27, 2020), as amended and extended by the Taxpayer Certainty and Disaster Tax Relief Act of 2020 (Relief Act), enacted as Division EE of the Consolidated Appropriations Act, 2021, provided relief to taxpayers from economic hardships resulting from the Coronavirus Disease 2019 (COVID–19), including paid sick and family leave credits to eligible employers with respect to qualified leave wages paid for a period of leave taken beginning April 1, 2020, and ending March 31, 2021, and an employee retention credit (ERC) with respect to qualified wages paid after March 12, 2020, and before July 1, 2021, respectively. The American Rescue Plan Act of 2021 (ARP), Public Law 117–2, 135 Stat. 4 (March 11, 2021), provided additional COVID–19 relief with similar paid leave credits under sections 3131 through 3133 of the Code, enacted by section 9641 of the ARP, with respect to qualified leave wages paid for a period of leave taken beginning April 1, 2021, and ending September 30, 2021, and a substantially similar ERC under section 3134 of the Code, enacted by section 9651 of the ARP, with respect to qualified wages paid after June 30, 2021, and before January 1, 2022.[1]

[1] Section 80604 of the Infrastructure Investment and Jobs Act (Infrastructure Act), Public Law 117–68, 135 Stat. 429 (November 15, 2021) amended section 3134(n) of the Code to provide that the ERC under section 3134 applies only to wages paid after June 30, 2021, and before October 1, 2021 (or, in the case of wages paid by an eligible employer which is a recovery startup business, January 1, 2022). Therefore, the only type of employer eligible for the ERC for wages paid after September 30, 2021, and before January 1, 2022, is an employer that meets the definition of a recovery startup business under section 3134(c)(5). *See* Notice 2021–