TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
	No new entries at this time.	
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
	No new entries at this time.	
	R. Sterility	
14–586	Sterilization of health care products—Low temperature vaporized hydrogen peroxide—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 22441 First edition 2022–08.
14–587	Guidance on transferring health care products between radiation sterilization sources	AAMI TIR104:2022.
14–588	Compatibility of materials subjected to sterilization	AAMI TIR17:2017/(R)2020.
	S. Tissue Engineering	
	No new entries at this time.	

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16770 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3032]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous Oxide (N_2O); Carisoprodol; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is inviting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of eight drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Either electronic or written comments must be submitted by August 24, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3032 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3-CMC); Dipentylone; 2-Fluorodeschloroketamine (2-FDCK); Nitrous oxide (N_2O); Carisoprodol; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Edward (Greg) Hawkins, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5110, Silver Spring, MD 20993–0002, 301–796–0727, *edward.hawkins@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (nonrelevant text removed):

Ref.: C.L.22.2023

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of announcing that the 46th Expert Committee on Drug Dependence (ECDD) will meet from 16 to 20 October 2023, in Geneva, Switzerland. Given that WHO Expert Committee meetings are of a closed nature, this letter serves to notify Member States of the substances under review at the 46th ECDD, which are in the Annex I file, attached for reference.

WHO is mandated by the 1961 and 1971 International Drug Control Conventions to make recommendations to the UN Secretary-General on the need for and level of international control of psychoactive substances based on the advice of its independent scientific advisory body, the ECDD. To assess whether or not a psychoactive substance should be placed under international control, the ECDD convenes annually to review the potential of this substance to cause dependence, abuse and harm to health, as well as any therapeutic applications. In order to perform this review and make evidence-based decisions, the ECDD conducts medical, scientific, and public health evaluations of the selected psychoactive substances using the best available information.

Although the meetings are of a closed nature, Member States are invited to contribute to the ECDD review process by joining the 46th ECDD Information Session on 16 October 2023. The Information Session will be held virtually and allow interested parties to learn about present and future activities of the ECDD Secretariat, and to present information concerning substances under review to the 46th Expert Committee

for consideration in its deliberations. Registration information will be made available on the ECDD website in due course: *https://www.who.int/news-room/events/detail/2023/10/16/default-calendar/forty-sixth-expert-committee-on-drug-dependence.*

As in the past and in line with the publication ''*Guidance on the WHO review of psychoactive substances for international control*'' (EB126/2010/REC1, Annex 6),[1] Member States can also contribute to the ECDD review process by providing up to date and accurate information concerning the substances under review in advance of the meeting. For this purpose, and as per previous practice, a questionnaire will be sent to Member States to gather country information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 27 June 2023

[1] *https://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=90.*

Annex I

46th Expert Committee on Drug Dependence (ECDD) Substances for Review 16–20 October 2023

Critical reviews: The substances listed below have been proposed by WHO for critical review and are not currently under international control. Information was brought to WHO's attention that these substances are clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Party. The Expert Committee will consider whether information presented during a critical review may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions.

Benzodiazepines
1. Bromazolam
2. Flubromazepam

Novel Synthetic Opioids
3. Butonitazene

Cathinones/stimulants
4. 3-Chloromethcathinone (3-CMC)
5. Dipentylone

Dissociative-type substances
6. 2-fluorodeschloroketamine (2-FDCK)

Pre-reviews: The substances listed below have been proposed for a pre-review. The purpose of a pre-review is to determine whether current information justifies an Expert Committee critical review. A pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed.

Medicines
7. Nitrous oxide
8. Carisoprodol

FDA has verified the website addresses contained in the WHO notice as of the date this document publishes in the **Federal Register**; however, websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/groups/who-expert-committee-on-drug-dependence/46th-ecdd-documents.*

III. Substances Under WHO Review

Bromazolam is a triazolobenzodiazepine that produces agonist effects on gamma-aminobutyric acid (GABA) type-A channels through the benzodiazepine site. Through this mechanism of action, bromazolam can produce sedative and anxiolytic effects similar to other drugs of the benzodiazepine class. According to the National Forensic Laboratory Information System (NFLIS) database, there were 2,881 drug seizures of bromazolam in the United States from 2016 to May of 2023; however, some case reports are still pending for 2022 and 2023, so this number is increasing. Toxicology data indicate that bromazolam is typically detected in samples that include other drugs such as stimulants and opioids. This polydrug combination has led to the determination that bromazolam has played at least a contributory role in 152 confirmed deaths associated with the use of bromazolam. There are no commercial or approved medical uses for bromazolam in the United States, and it is not controlled under the CSA.

Flubromazepam is a compound of the benzodiazepine class that produces agonist effects on $GABA_A$ channels and can produce sedative and anxiolytic effects similar to other drugs of the class. Law enforcement data indicate that flubromazepam has been detected in 169 biological samples from 2019 through 2022. In 2022, 87 percent of those samples also contained fentanyl. There are no commercial or approved medical uses for flubromazepam in the United States and it is not controlled under the CSA.

Butonitazene is a novel synthetic mu-opioid receptor agonist of the benzimidazole structural class. Law enforcement data indicates that butonitazene appeared on the U.S. illicit markets as evidenced by their identification in forensic drug seizures and biological samples. The abuse liability of benzimidazole opioids is similar to other synthetic opioids. Butonitazene has been identified in toxicological samples from post-mortem cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established and can result in drowsiness, nausea, vomiting, and respiratory depression leading to death. Butonitazene has no approved medical uses in the United States and is a schedule I substance under the CSA.

3-Chloromethcathinone (3-CMC) and dipentylone are synthetic stimulant designer drugs structurally similar to schedule I synthetic cathinones and schedule II stimulants like methamphetamine. Like other schedule I synthetic cathinones, 3-MMC and dipentylone are abused for their psychoactive effects. Adverse effects associated with the abuse of synthetic cathinones include agitation, hypertension, tachycardia, and death. According to NFLIS, dipentylone was first detected in the United States in 2014, and in 2022 there were 4,901 law enforcement seizures of the drug. Both 3-CMC and dipentylone have been detected in biological samples from toxicological drug tests and from postmortem samples. 3-CMC and dipentylone have no approved medical uses in the United States and both are schedule I substances under the CSA.

2-Fluorodeschloroketamine (2-FDCK) is a dissociative anesthetic related to ketamine. 2-FDCK is a novel psychoactive substance (NPS) that is used as a research chemical and is sometimes marketed as a legal high. In animals, 2-FDCK demonstrated a similar potential for abuse as ketamine in studies that compare measurements of reinforcing effects (*e.g.,* self-administration) and discriminative stimulus effects (*e.g.,* drug discrimination and conditioned place preference). As a result, 2-FDCK is presumed to produce psychoactive effects similar to ketamine such as sensory dissociation, derealization, analgesia, hallucinations, mania, and amnesia. 2-FDCK has been detected in biological samples from toxicological drug tests and from postmortem samples. 2-FDCK has no approved medical uses in the United States and is not a controlled substance under the CSA, although it is controlled in many European countries.

Nitrous oxide (N_2O) is an inhalable gas that is also known by the common names, laughing gas, nitrous, whippets, NOS, or hippy-crack. It is part of the dissociative class of hallucinogens and is thought to function through modulation of GABA and *N*-methyl-*D*-aspartate (NMDA) receptors. N_2O was first used in the late 1700s as an analgesic for dental and surgical operations. It is approved by FDA as a medical gas but has seen increasing use around the world for its subjective effects. These effects include, but are not limited to, dizziness, loss of motor control, euphoria, perceptual changes, numbness, amnesia, derealization, and altered acuity. N_2O is not controlled under the CSA.

Carisoprodol is a sedative-hypnotic that is used as a centrally acting muscle relaxant and hypnotic. Carisoprodol is a prodrug that is metabolized in the liver to form meprobamate which functions similarly to benzodiazepines and barbiturates. It is approved for medical use in the United States as a muscle relaxant and is typically prescribed in combination with analgesics to treat muscle pain. Scientific studies indicate that carisoprodol has a demonstrated abuse potential similar to benzodiazepines, and it is controlled under schedule IV under the CSA.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the eight drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2023. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA (21 U.S.C. 811).

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16812 Filed 8–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–0038]

Determination That CUBICIN (Daptomycin) Powder for Injection, 250 Milligrams/Vial and 500 Milligrams/Vial, and CUBICIN RF (Daptomycin) Powder for Injection, 500 Milligrams/Vial, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CUBICIN (daptomycin) Powder for Injection, 250 milligrams (mg)/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for daptomycin powder for injection, 250 mg/vial and 500 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993–0002, 202–768–5659, *tereza.hess@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, initially approved on September 12, 2003, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, initially approved on July 6, 2016, are the subjects of NDA 021572, held by Cubist Pharmaceuticals, LLC. CUBICIN and CUBICIN RF are indicated for treatment of complicated skin and skin structure infections in adult and pediatric patients (1 to 17 years of age), and *Staphylococcus aureus* bloodstream infections (bacteremia) in adult patients including those with right-sided infective endocarditis. CUBICIN is also indicated for treatment of *S. aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated June 22, 2021, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated March 30, 2022, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN (daptomycin) Powder for Injection, 500 mg/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 3, 2023 (Docket No. FDA–2023–P–0038), under 21 CFR 10.30, requesting that the Agency determine whether CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial