interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members); or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than most of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/blood-products-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16577 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1625]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-BUTINACA; Adinazolam; Bromazolam; Protonitazene (Propoxynitazene); Etazene (Etodesnitazene); Etonitazepyne (N-Pyrrolidino etonitazene); 2-Methyl-AP-237; Alpha-PiHP; 3-Methylmethcathinone (3-MMC); Zopiclone; 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 10 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, 2022.

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, 2022. 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–2022–N–1625 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB-BUTINACA; Adinazolam; Bromazolam; Protonitazene (propoxynitazene); Etazene (etodesnitazene); Etonitazepyne (N-pyrrolidino etonitazene); 2-Methyl-AP-237; alpha-PiHP; 3-Methylmethcathinone (3-MMC); Zopiclone; 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. 5150, 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.

Section 201(d)(2)(A) of the CSA (21 U.S.C. 811(d)(2)(A)) (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.27.2022

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of announcing that the 45th Expert Committee on Drug Dependence (ECDD) will meet from 10 to 14 October 2022, 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 45th ECDD, which are in the Annex I, 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 45th ECDD Open Session on 10 October 2022. 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 Expert Committee for consideration in its deliberations. Registration information will be made available on the ECDD website in due course: *https://www.who.int/medicines/access/controlled-substances/en/.*

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 accurate information concerning the substances under review in advance of the meeting. For this purpose, 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.

In addition to the questionnaire, Member States are also encouraged to provide any additional relevant information (unpublished or published) on substances to be reviewed by the 45th ECDD.

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

GENEVA, 10 June 2021

[1] *https://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=58.*

Annex I

45th Expert Committee on Drug Dependence (ECDD) Substances For Review 10–14 October 2022

Critical reviews: The substances listed below have never been formally reviewed by WHO 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.

Synthetic cannabinoid receptor agonists

1. ADB–BUTINACA

Benzodiazepines

2. Adinazolam
3. Bromazolam

Novel synthetic opioids

4. Protonitazene (propoxynitazene)
5. Etazene (etodesnitazene)
6. Etonitazepyne (N-pyrrolidino etonitazene)
7. 2-Methyl-AP–237

Cathinones/stimulants

8. alpha-PiHP
9. 3-Methylmethcathinone (3–MMC)

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

1. Zopiclone

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/publications/m/item/45th-ecdd-questionnaire.*

III. Substances Under WHO Review

ADB–BUTINACA is a synthetic cannabinoid that has been sold online and is used to mimic the biological effects of tetrahydrocannabinol, the

main psychoactive constituent in marijuana. Research and clinical reports have demonstrated that synthetic cannabinoids are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high.'' Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. According to the National Forensic Laboratory Information System (NFLIS-Drug) database,[1] ADB–BUTINACA was first reported in 2020, and there were 4,358 reports in 2021. There are toxicology reports identifying ADB–BUTINACA in at least six deaths and eight non-fatal emergency room visits. There are no commercial or approved medical uses for ADB–BUTINACA. As a positional isomer of AB–PINACA, ADB–BUTINACA is controlled in schedule I of the CSA.

Adinazolam is a designer benzodiazepine (*i.e.,* a structural or functional analog of other drugs in the benzodiazepine class) and is expected to have central nervous system (CNS) depressant-like effects similar to that of other known benzodiazepines. Adinazolam was first reported to NFLIS-Drug in 2019, and there were 87 reports in 2021. Adinazolam has appeared in toxicology reports in the United States. Adinazolam is not currently controlled in the United States.

Bromazolam is a designer benzodiazepine and is expected to have CNS depressant-like effects similar to that of other known benzodiazepines. Bromazolam was first reported to NFLIS-Drug in 2016, and there were 743 reports in 2021. Bromazolam has appeared in at least two overdose death reports in the United States and adverse effects associated with the use of bromazolam have been reported. Bromazolam is not currently controlled in the United States.

Protonitazene (propoxynitazene), etazene (etodesnitazene), and etonitazepyne (*N*-pyrrolidino etonitazene) are novel synthetic opioid receptor agonists of the benzimidazole structural class. Law enforcement data indicates that these substances have appeared on the U.S. illicit markets as evidenced by their identification in forensic drug seizures and biological samples. Etazene was first reported to NFLIS-Drug in 2020, and there were 41 reports in 2021. Protonitazene and etonitazepyne were both first reported to NFLIS-Drug in 2021 with 20 and 129 reports in that year, respectively. The abuse of these benzimidazole opioids are similar to other synthetic opioids. Protonitazene, etazene, and etonitazepyne have been identified in toxicology and several post-mortem cases. The public health risks attendant to the abuse of mu-opioid receptor agonists are well established. These risks included large numbers of drug treatment admissions, emergency department visits, and fatal overdoses. On April 12, 2022, the U.S. Drug Enforcement Administration issued a temporary order to control these substances as schedule I substances under the CSA.

2-Methyl-AP-237 is a novel synthetic mu-opioid receptor agonist. It was first reported to NFLIS-Drug in 2019, and there were 45 reports in 2021. Abuse of 2-methyl-AP-237 is similar to other synthetic opioids, and has been associated with adverse health effects, including death. In the United States, there are at least 10 confirmed reports of fatal poisonings and several reports of emergency room visits, and non-fatal poisonings associated with 2-methyl-AP-237. 2-Methyl-AP-237 is not currently controlled in the United States. There are no commercial or approved medical uses of 2-methyl-AP-237.

Alpha-PiHP is a synthetic stimulant designer drug structurally similar to other schedule I synthetic cathinones. Alpha-PiHP is a monoamine transporter (dopamine transporter and norepinephrine transporter) uptake inhibitor. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. Alpha-PiHP was first reported to NFLIS-Drug in 2017, and there were 332 reports in 2021. Alpha-PiHP has been confirmed to have played a role in fatal and non-fatal overdose events in the United States. Alpha-PiHP has no approved medical uses in the United States. As a positional isomer of alpha-PHP, alpha-PiHP is controlled in schedule I of the CSA.

3-Methylmethcathinone (3-MMC) is a designer drug of the phenethylamine class, which is structurally and pharmacologically similar to amphetamine, 3,4-methylenedioxymethamphetamine, cathinone and other related substances. 3-MMC is a monoamine transporter (dopamine transporter, serotonin transporter, and norepinephrine transporter) uptake inhibitor. Like other schedule I synthetic cathinones, 3-MMC is abused for its psychoactive effects. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. 3-MMC was first reported to NFLIS-Drug in 2012, and there were three reports in 2021. 3-MMC has no approved medical uses in the United States. As a positional isomer of mephedrone, 3-MMC is controlled in schedule I of the CSA.

Zopiclone is a nervous system depressant drug used in the treatment of insomnia. Its mechanism of action is based on modulating benzodiazepine receptors. Zopiclone is approved for medical use in the United States as (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone. Zopiclone has abuse potential and may be misused due to its ability to produce euphoric effects at high doses. Amnesia and hallucinations have been reported with higher doses. Zopiclone is controlled in schedule IV of the CSA.

IV. Opportunity To Submit Domestic Information

As required by section 201(d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 10 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 2022. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by section 201(d)(2)(B) of the CSA.

[1] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects drug identification results from drug cases submitted to and analyzed by Federal, State and local forensic laboratories in the United States. NFLIS-Drug data were queried on June 29, 2022.

Dated: July 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16572 Filed 8–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1173]

Electronic Submission of Expedited Safety Reports From Investigational New Drug-Exempt Bioavailability/ Bioequivalence Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Electronic Submission of Expedited Safety Reports From IND-Exempt BA/BE Studies.'' This guidance provides instructions for the electronic submission of expedited individual case safety reports (ICSRs) from investigational new drug (IND)-exempt bioavailability (BA)/bioequivalence (BE) studies through the FDA Adverse Event Reporting System (FAERS) database.

DATES: Submit either electronic or written comments on the draft guidance by October 3, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2022–D–1173 for ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies.'' This guidance provides instructions for the electronic submission of expedited ICSRs from IND-exempt BA/BE studies through the FAERS database. An ICSR captures information necessary to support the reporting of an adverse event related to an individual subject that is associated with the use of an FDA-regulated product.[1] The electronic submission of the ICSRs from IND-exempt BA/BE studies is a voluntary option.

In the **Federal Register** of September 29, 2010 (75 FR 59935), FDA published a final rule that revised the IND safety reporting requirements for human drug and biological products under 21 CFR 312 and added safety reporting requirements for persons conducting

[1] See additional information on Individual Case Safety Reports available at *https://www.fda.gov/industry/fda-resources-data-standards/individual-case-safety-reports.*