behaviors, tachycardia, and hypertension. There are no commercial or approved medical uses for MDMB-4en-PINACA and it is not a controlled substance under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if MDMB-4en-PINACA is controlled under Schedule II of the 1971 Convention.

3-Methoxyphencyclidine; chemical name: 1-(1-(3-methoxyphenyl) cyclohexyl)piperidine) is a novel N-methyl-D-aspartate (NMDA) receptor antagonist with structural and biochemical similarities to phencyclcycidine (PCP) and other arylcyclohexylamines. 3-Methoxyphencyclidine is classified as an arylcyclohexylamine and produces dissociative anesthetic and hallucinogenic effects. Use of this substance is associated with intoxication and published case reports of both fatal and non-fatal overdose. 3-Methoxyphencyclidine is encountered by law enforcement in drug seizure reports. 3-Methoxyphencyclidine is an analogue of the Schedule II hallucinogen PCP. There is no approved medical use for 3-Methoxyphencyclidine in the United States and is not a controlled substance under the CSA. If intended for human consumption, 3-Methoxyphencyclidine may be treated as a ''controlled substance analogue'' under the CSA pursuant to 21 U.S.C. 802(32)(A) and 813. As such, additional permanent controls will be necessary to fulfill U.S. obligations if 3-Methoxyphencyclidine is controlled under Schedule II of the 1971 Convention.

Diphenidine (chemical name: 1-(1,2-diphenylethyl) piperidine) is a non-competitive NMDA receptor antagonist classified as a diarylethylamine and produces dissociative anesthetic and hallucinogenic effects. It was originally synthesized in the 1920s but reports of abuse started in the last decade. Use of this substance is associated with intoxication and published case reports of both fatal and non-fatal overdose outside of the United States. Diphenidine is encountered by law enforcement in drug seizure reports. Diphenidine is not approved for medical use in the United States and is not a controlled substance under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if diphenidine is controlled under Schedule II of the 1971 Convention.

Flubromazolam, clonazolam, and diclazepam belong to a class of substances known as benzodiazepines. Benzodiazepines produce central nervous system depression and are commonly used to treat insomnia, anxiety, and seizure disorders. Flubromazolam is a triazole analogue of the designer benzodiazepine, flubromazepam. Flubromazolam can be purchased on the internet and is used as a recreational substance in the United States. Flubromazolam has been identified in an increasing number of law enforcement seizures and has been associated with an increasing number of drug overdose deaths. According to the NFLIS database, in 2020 there were 1,446 clonazolam encounters (as of December 2020). It is abused by a broad range of groups including youths, young adults, and older adults. Clonazolam has been involved in an increasing number of drug seizure events as well as drug overdose deaths, alone and in combination with alcohol. As such, the NFLIS database reported 249 encounters in 2020 (as of December 2020). Diclazepam is a designer benzodiazepine sold on the internet and most often found as a liquid solution, but it may be sold as a powder, tablet, blotter paper, or pellet. In 2020, the NFLIS database reported 113 encounters of diclazepam (as of December 2020). In 2018, flubromazolam, clonazolam, and dicalazepam were all identified by law enforcement in driving under the influence of drugs cases in the United States. Flubromazolam, clonazolam, and diclazepam are not approved for medical use in the United States and are not controlled substances under the CSA. As such, additional permanent controls will be necessary to fulfill U.S. obligations if flubromazolam, clonazolam, and dicalazepam are controlled under Schedule IV of the 1971 Convention.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the notifications from the United Nations concerning these drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, under section 201(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations for control of substances under the 1971 Convention at the CND meeting in April 2021.

Comments regarding the WHO recommendations for control of isotonitazene under the 1961 Single Convention will also be forwarded to the relevant Agencies for consideration in developing the U.S. position regarding narcotic substances at the CND meeting.

Dated: February 12, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03268 Filed 2–17–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP21–008, Examining Approaches to Improve Care and Management of People with Lupus.

Date: May 13, 2021.

Time: 11:00 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

FOR FURTHER INFORMATION CONTACT: Jaya Raman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341, Telephone (770) 488–6511, *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–03234 Filed 2–17–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification To Accompany Drug, Biological Product, and Device Applications or Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 22, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0616. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

OMB Control Number 0910–0616—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and already approved by OMB. The OMB control numbers and expiration dates for those applications and submissions are: 21 CFR parts 312 and 314 (human drugs), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0001, expiring March 31, 2021; 21 CFR parts 312 and 601 (biological products), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0338, expiring February 28, 2023; 21 CFR parts 807 and 814 (devices), OMB control number 0910–0120, expiring June 30, 2020, and OMB control number 0910–0231, expiring March 31, 2023.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) amended the PHS Act by adding section 402(j). The provisions broadened the scope of clinical trials subject to submitting information and required additional information to be submitted to the clinical trials databank (*https://clinicaltrials.gov/*) (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website after this document publishes in the **Federal Register**) previously established by the National Institutes of Health (NIH)/National Library of Medicine. This includes expanded information on applicable clinical trials and summary information on the results of certain clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at *https://clinicaltrials.gov/.*

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification, are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties. Form FDA 3674 provides a convenient mechanism for sponsors/applicants/submitters to satisfy the certification requirements of the statutory provision.

To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.* This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. FDA last updated this guidance in 2017.

Investigational New Drug Applications. FDA's Center for Drug Evaluation and Research (CDER) received 1,661 investigational new drug applications (INDs) and 11,328 clinical protocol IND amendments in calendar year (CY) 2019. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 639 new INDs and 581 clinical protocol IND amendments in CY 2019. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future. The estimated total number of submissions (new INDs and new