

2022, ACIP meeting must submit a request at <https://www.cdc.gov/vaccines/acip/meetings/index.html> no later than 11:59 p.m., EDT, June 13, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by June 15, 2022. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may speak only once per meeting.

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. 2022-09950 Filed 5-9-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP22-005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance To Support Climate and Health Adaptation Planning; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP22-005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning; May 4, 2022, 11 a.m.–6 p.m., EDT, in the original FRN.

The meeting was published in the **Federal Register** on March 1, 2022, Volume 87, Number 40, page 11444.

The meeting is being amended to change the meeting date and time and should read as follows:

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP22-005, Building Resilience Against Climate Effects (BRACE): Enhancing Practical Guidance to Support Climate and Health Adaptation Planning.

Date: May 19, 2022.

Time: 3 p.m.–6 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

The meeting is closed to the public.

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102-3.150(b), less than 15 calendar days' notice is being given for this amended closed meeting due to an unforeseen medical emergency and exceptional circumstances that led to an anomaly of programmatic matters and the necessity to resolve issues, reschedule, and convene as soon as possible.

FOR FURTHER INFORMATION CONTACT: Jaya Raman, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, Mailstop F80, Atlanta, Georgia 30341, Telephone: (770) 488-6511, kva5@cdc.gov.

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Kalwant Smagh,

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

[FR Doc. 2022-10023 Filed 5-9-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10286 & CMS-10630]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing

an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 9, 2022*.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS-10286, OMB control number: 0938-1077; *Frequency:* On Occasion; *Affected Public:* Private Sector; State, Local or Tribal governments; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 1. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The PACE Organization (PO) Monitoring and Audit

Process in 42 CFR part 460; *Use:* Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR 460.190 and 460.192 state that CMS, in conjunction with the State Administering Agency (SAA), must oversee a PACE organization's continued compliance with the requirements for a PACE organization.

The data collected with the data request tools included in this package allow CMS to conduct a comprehensive review of PACE organizations' compliance in accordance with specific federal regulatory requirements. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive the audit results, and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS-10630 (OMB control number: 0938-1327); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments and Business or other for-profit institutions; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours:* 31,200. (For policy questions regarding this collection contact Kathleen Flannery at 410-786-6722.)

Dated: May 5, 2022.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022-10026 Filed 5-9-22; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-P-0939]

Determination That GLUCOTROL (Glipizide) Tablets, 2.5 Milligrams, 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, Agency, or we) has determined that GLUCOTROL (glipizide) tablets, 2.5 milligrams (mg), were not withdrawn from sale for

reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for glipizide tablets, 2.5 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Dan Ritterbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993-0002, 301-796-4673, Daniel.Ritterbeck@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.

GLUCOTROL (glipizide) tablets, 2.5 mg, are the subject of NDA 017783, held by Pfizer Inc., and initially approved on May 8, 1984. GLUCOTROL is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.