Biological Products'' issued on December 20, 2019 (84 FR 70196) and the 1998 guidance entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' issued on May 15, 1998 (63 FR 27093).

In 1962, Congress required for the first time that new drugs be shown to be effective as well as safe. A new drug's effectiveness must be established by substantial evidence. FDA has interpreted this substantial evidence requirement as generally requiring two adequate and well-controlled clinical investigations, each convincing on its own, to establish effectiveness.

In 1997, Congress amended section 505(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(d)) to make clear that FDA may consider data from one adequate and well-controlled investigation and confirmatory evidence to constitute substantial evidence if FDA determines that such data are sufficient to establish effectiveness. FDA issued the 1998 Effectiveness guidance in response to this legislative change. In 2019, the Agency concluded that more guidance was needed on the flexibility in the amount and type of evidence needed to meet the substantial evidence standard and issued the 2019 Effectiveness draft guidance, which discussed a number of approaches that can yield evidence that meets the statutory standard for substantial evidence.

Although both the 1998 Effectiveness guidance and the 2019 Effectiveness draft guidance provide examples of how a single adequate and well-controlled clinical investigation and confirmatory evidence can be used to support a marketing application, these guidances are not intended to provide a comprehensive discussion of meeting the substantial evidence standard based on one adequate and well-controlled clinical investigation and confirmatory evidence. Thus, there is a need for more Agency guidance to describe how one adequate and well-controlled clinical investigation and confirmatory evidence can be used to meet the substantial evidence requirement.

When one adequate and well-controlled clinical investigation and confirmatory evidence are considered together to assess effectiveness, the quality and quantity of the confirmatory evidence are also important considerations. Confirmatory evidence should be evidence generated from quality data derived from an appropriate source. The quantity of confirmatory evidence needed in a development program will be impacted by the features of, and results from, the single adequate and well-controlled clinical investigation that the confirmatory evidence is intended to substantiate.

This draft guidance describes these considerations in greater detail. It also provides examples of the types of evidence that could be considered confirmatory evidence that can be used with one adequate and well-controlled clinical investigation to demonstrate substantial evidence of effectiveness. Finally, the draft guidance includes recommendations for early engagement with the Agency for sponsors who intend to establish substantial evidence of effectiveness with one adequate and well-controlled clinical investigation and confirmatory evidence.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 58, 312, 314, and 601 have been approved under OMB control numbers 0910–0119, 0910–0014, 0910–0001, and 0910–0338, respectively. In addition, the collections of information pertaining to FDA's guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 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. 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: National Institute on Aging Special Emphasis Panel; Interorgan signal.

Date: October 19–20, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, (301) 496–9667, *prasadnb@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 14, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–20239 Filed 9–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Digestive Diseases