guidance is to assist sponsors in the clinical development of fixed combination drug products for the treatment of hypertension. The guidance focuses on development of two-drug combinations of previously approved drug products. This guidance incorporates the comments received for and finalizes the draft guidance for industry entitled ''Hypertension: Developing Fixed-Dose Combination Drugs for Treatment'' issued on January 26, 2018 (83 FR 3735). All the public comments received on the draft guidance have been considered, and the guidance was revised as appropriate primarily for editorial changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Hypertension: Developing Fixed-Combination Drug Products for Treatment.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 has been approved under OMB control number 0910–0014. The collection of information in the guidance for industry entitled ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm075072.pdf*) has been approved under OMB control number 0910–0670.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: November 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24315 Filed 11–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, November 19, 2018, 8:30 a.m. to November 19, 2018, 4:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 which was published in the **Federal Register** on October 30, 2018, 83 FR 54605.

The meeting notice is amended to change the meeting location from the National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892 to Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814. The meeting is closed to the public.

Dated: November 1, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–24293 Filed 11–6–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request: Data and Specimen Hub (DASH) (Eunice Kennedy Shriver National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Rohan Hazra, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, 6710B Rockledge Drive, Room 2113, Bethesda, MD 20817, or call non-toll-free number (301)–435–6868 or Email your request, including your address to: *rohan.hazra@nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 27, 2018, page 18576 (Vol 83) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Data and Specimen Hub (DASH) 0925–0774 exp. date 6/30/19—REVISION; *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection:

This is a request to revise the previously approved submission to add the collection of additional information from Users who will request biospecimens, submit the Institutional Certification for data/biospecimen inventory, and submit DASH data/biospecimen Annual Progress Report for the NICHD Data and Specimen Hub (DASH). DASH has been established by NICHD as a data sharing mechanism for biomedical research investigators. It serves as a centralized resource for investigators to store and access deidentified study data and biospecimen inventories—a list of biospecimens available at the NICHD