201(ff)(3)(B)(i) of the FD&C Act (21 U.S.C. 321(ff)(3)(B)(i)), NAC is excluded from the dietary supplement definition because NAC was approved as a new drug before it was marketed as a dietary supplement or as a food. We described that FDA denied two citizen petitions requesting that we conclude that NAC is not excluded from the definition of dietary supplement under section 201(ff)(3)(B) of the FD&C Act.

In addition, we described that one citizen petition asked FDA to issue a regulation that would determine NAC to be lawful under the FD&C Act. We described that we have not yet reached a final decision on this request, but are considering initiating rulemaking under section 201(ff)(3)(B) of the FD&C Act to permit the use of NAC in or as a dietary supplement (*i.e.,* to provide by regulation that NAC is not excluded from the definition of dietary supplement). If, among other considerations, we do not identify safety-related concerns as we continue our review of the available data and information, we are likely to propose a rule providing that NAC is not excluded from the definition of dietary supplement.

We gave interested parties an opportunity to submit comments by May 23, 2022, to ensure their comments would be considered before we began work on the final version of the guidance. We received comments on the draft guidance that misinterpreted the guidance as converting NAC into a ''drug'' under the FD&C Act. Our guidance does not convert NAC into a ''drug'' under the FD&C Act. Rather, our guidance states our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements. We also received comments that supported our intent to exercise enforcement discretion with respect to the sale and distribution of certain products that contain NAC and are labeled as dietary supplements, as well as comments that supported possible notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement. After careful review and consideration of the comments to the draft guidance, we are finalizing the guidance without substantive change.

As discussed in the guidance, the enforcement discretion policy applies to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of ''dietary supplement'' and that are not otherwise in violation of the FD&C Act. Unless we identify safety-related concerns during our ongoing review, FDA intends to exercise enforcement discretion until either of the following occurs: we complete notice-and-comment rulemaking to allow the use of NAC in or as a dietary supplement (if we move forward with such proceedings), or we deny the citizen petition's request for rulemaking. Should we determine that this enforcement discretion policy is no longer appropriate, we will withdraw or revise this guidance in accordance with 21 CFR 10.115.

The guidance announced in this notice finalizes the draft guidance, dated April 2022.

II. Paperwork Reduction Act of 1995

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/FoodGuidances, https://www.fda.gov/CosmeticGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: July 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16499 Filed 8–1–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0478]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 1, 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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–0478 30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Unified Hospital Data Surveillance System (U.S. Healthcare COVID–19 Collection).

Type of Collection: Emergency Revision.

OMB No.: 0990–0478.

Abstract: Since March 29, 2020, the U.S. government has been collecting data from hospitals and states to understand health care system stress, capacity, capabilities, and the number of patients hospitalized due to COVID–19. The principal use of the data collected through this ICR is to inform federal allocations of limited supplies (*e.g.,* protective equipment and medication). It is also used to inform the White House, conduct research on hospitalization, and communicate to the public through daily and weekly reports for the public's use and analysis.

Hospitals, with the exception of psychiatric and rehabilitation hospitals, are required to report seven days a week but, where possible and pending further direction from their state or jurisdiction, are encouraged to report weekend data on the following Monday with the data backdated to the appropriate date. Data elements may be required or optional and may be associated with a specific cadence. Some data elements are requested at each reporting interval (*i.e.,* daily), while others are requested weekly. As of the August 10, 2022 guidance, per Secretary discretion, psychiatric and rehabilitation facilities must submit data once annually for the

week prior to meet federal reporting requirements. This may evolve based on the needs of the national response. All hospitals are asked to follow the direction of their state and jurisdiction to ensure reporting meets state, tribal, local, and territorial (STLT) needs. This collection will continue for the length of the public health emergency declaration.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Hospitals (excluding Psychiatric and Rehabilitation Hospitals)	5,200	365	1.1	2,087,800
Psychiatric and Rehabilitation Hospitals	870	1	1.1	957
Total				2,088,757

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–16505 Filed 8–1–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: 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. 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 Glial Pathology in Brain Aging.

Date: October 4, 2022.

Time: 12:00 p.m. to 4:30 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: Alexander Parsadanian, Ph.D., Scientific Review Officer National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue Bethesda, MD 20892, 301–496–9666 *Parsadaniana@nia.nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

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

Dated: July 26, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–16468 Filed 8–1–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes on Aging: 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. 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; Alzheimer's Disease Drug Development.

Date: October 21, 2022.

Time: 12:00 p.m. to 2:30 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: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *PARSADANIANA@NIA.NIH.GOV*.

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

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

Dated: July 26, 2022.

David W Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–16470 Filed 8–1–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2258]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community