existing information in the labeling for a currently approved drug in a supplement to such applications.

This draft guidance provides examples of required and recommended information in the DOSAGE AND ADMINISTRATION section. This guidance provides recommendations on including certain dosage- and administration-related information in the DOSAGE AND ADMINISTRATION section that is particularly critical to the safe and effective use of the drug (*e.g.,* lack of knowledge of the information or nonadherence to a recommendation could have serious consequences for patients).

This draft guidance addresses the dosage and route of administration for each indication in the DOSAGE AND ADMINISTRATION section and information about the dosage range, the starting or loading dose and dosage, titration schedule, the maximum recommended dosage, the maximum recommended duration, monitoring for effectiveness, and concomitant therapy information in the DOSAGE AND ADMINISTRATION section, as appropriate.

This draft guidance also addresses the following information in the DOSAGE AND ADMINISTRATION section:

- Other drugs used before, during, or after drug treatment or administration;
- Dosage modifications for adverse reactions or for drug interactions;
- Dosage in specific populations (*e.g.,* pediatric patients, geriatric patients, patients with renal impairment, patients with hepatic impairment);
- Information about switching to the subject drug from other products or substitution involving the subject drug;
- Recommendations regarding missed dose(s);
- Recommendations in event of vomiting after oral drug administration;
- Recommendations for drug discontinuation or dosage reduction when there are risks of withdrawal; and
- The recommended dosage for fixed-combination drug products and co-packaged products.

Furthermore, this draft guidance addresses when and how to include information in the DOSAGE AND ADMINISTRATION section on the preparation and/or administration of the drug (*e.g.,* parenteral products, a product stored in the refrigerator or freezer, pharmacy bulk packages, imaging bulk packages, solid oral dosage forms with qualified liquids or soft foods, oral dosage forms via enteral feeding tubes, liposome drug products); instructions to avoid harm related to drug handling and administration, radiation dosimetry; and information on drug incompatibilities if the drug is mixed with other drugs. This guidance also provides information on storage instructions for the reconstituted or diluted product.

Finally, this draft guidance describes information that should ordinarily not be included in the DOSAGE AND ADMINISTRATION section.

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 the ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' 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

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 314 and 21 CFR 601 have been approved under OMB control number 0910–0001 and 0910–0338. The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

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/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: January 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00619 Filed 1–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0945–0008]

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 February 13, 2023.

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 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) 264–0041. When submitting comments or requesting information, please include the document identifier 0990-New-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.

Type of Collection: Reinstatement with changes.

OMB No.: 0945–0008.

Abstract: This Information Collection Request is for a reinstatement with changes to previously approved collection 0945–0008 that is expired in December 2022, titled: Assurance of Compliance, Form HHS–690, subject to minor modifications. Such an assurance is required by the federal civil rights laws enforced by the Office for Civil Rights, as described herein. One method that the federal government uses to ensure civil rights compliance is to require covered entities to submit written assurances of compliance when applying for federal financial assistance. The assurances alert covered entities of their civil rights obligations and provide the Department with a valuable enforcement tool, as a recipient's written assurance and certification documents can provide an independent

contractual basis for enforcement of nondiscrimination requirements. This is for a 3year request.

Type of Respondent; Affected Public: States, certain health care providers, other persons, or entities receiving/requesting Funding.

Frequency: The Applicant provides this Assurance of Compliance when it applies for or receives new HHS funds.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Avg. burden/response (in hours)	Total burden hours
States, certain health care providers, other persons, and entities.	Form HHS–690.	9595	1	4	38,380
Total					38,380

Sherrette A. Funn,

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

[FR Doc. 2023–00558 Filed 1–12–23; 8:45 am]

BILLING CODE 4150–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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

The meetings 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2021–1 Phase II: Rapid, Point of Care Molecular Diagnostics for HCV (Topic 99).

Date: February 6, 2023.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, (240) 669–5931, *jakesse@mail.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2021–1 Phase II: Development of Priority Diagnostics for Chagas Disease (Topic 96).

Date: February 7, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, (240) 669–5931, *jakesse@mail.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2023–1 Phase I: Adaptation of CRISPR-based in vitro Diagnostics for Rapid Detection of Select Eukaryotic Pathogens (Topic 119).

Date: February 9, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, (240) 669–5931, *jakesse@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–00595 Filed 1–12–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

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

The meetings 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 of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C Study Section Translational Neural, Brain, and Pain Relief Devices.

Date: February 6–7, 2023.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Boulevard, Bethesda, MD 20892, 301–496–9223, *Ana.Olariu@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; SEP—Translational Neural, Brain and Pain Relief Devices.

Date: February 7, 2023.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive