This guidance explains how FDA will issue and use an IR and a DRL during the assessment of an original ANDA under section 505(j) of the FD&C Act (21 U.S.C. 355(j)), as contemplated under GDUFA II. This guidance does not apply to an amendment made in response to a Complete Response Letter, a supplement, or an amendment to a supplement.

This guidance identifies the timing of FDA's issuance of an IR or a DRL and the effect FDA's issuance of an IR or a DRL will have on the assessment clock for a given assessment cycle.

This guidance finalizes the draft guidance entitled ''Information Requests and Discipline Review Letters Under GDUFA'' issued on December 18, 2017 (82 FR 60018). FDA considered comments received on the draft guidance as the guidance was finalized. Minor changes were made from the draft to the final guidance, primarily to reflect current terminology.

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 ''Information Requests and Discipline Review Letters Under GDUFA.'' 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 collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 314 for approval of abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information that support FDA's guidance for industry on controlled correspondence related to generic drug development have been approved under OMB control number 0910–0797.

III. Electronic Access

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

Dated: January 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01605 Filed 1–26–22; 8:45 am]

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Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Commitment Letter).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Research Study Section.

Date: February 28–March 2, 2022.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Mario Cerritelli, 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 3F58, Rockville, MD 20852, 240–669–5199, *cerritem@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 21, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–01549 Filed 1–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; NIA Multi-site Clinical Trial Implementation.

Date: February 22, 2022.

Time: 2:00 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: Isis S. Mikhail, MD, MPH, DrPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *MIKHAILI@MAIL.NIH.GOV.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Improving skin wounds' healing in aging.

Date: February 24, 2022.

Time: 9:30 a.m. to 2:00 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: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; ADNI 4.

Date: February 25, 2022.

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

Agenda: To review and evaluate grant applications.

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