specified the electronic format for submitting certain submission types to the Agency, such content must be submitted electronically and in the format specified by FDA. According to the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (available at *https://www.fda.gov/media/135373/download*), submissions subject to section 745A(a) of the FD&C Act must be submitted in eCTD format using the version of eCTD currently supported by FDA (unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver). The version of eCTD currently supported by FDA is specified in the Data Standards Catalog (available at *https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources*).

As described in the guidance for industry ''Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs'' (The Promotional Labeling Guidance) (available at *https://www.fda.gov/media/128163/download*), certain types of promotional-material-related submissions, including postmarketing submissions of promotional materials using Form FDA 2253 (required by § 314.81(b)(3)(i) (21 CFR 314.81(b)(3)(i)) and 21 CFR 601.12(f)(4)) (called 2253 submissions), fall within the scope of section 745A(a) of the FD&C Act and are, therefore, subject to the mandatory electronic submission requirements (unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver). The Promotional Labeling Guidance provides that 2253 submissions are required to be accompanied by a completed fillable Form FDA 2253. When submitting Form FDA 2253, firms must submit the most current product labeling, as required in § 314.81(b)(3)(i), under eCTD section 1.14.6, as described in the Promotional Labeling Guidance. Electronic Common Technical Document validations 1551 (''2253 submission does not include Product Labeling'') and 1553 (''The only valid FDA Form to include in a 2253 submission is FDA Form 2253'') describe parts of the eCTD specifications that were not followed correctly (see the Specifications for eCTD Validation Criteria, pp. 29 and 30, respectively). Submissions to CDER that are subject to section 745A(a) of the FD&C Act and fail to pass either eCTD validation 1551 or 1553 will begin being rejected on October 18, 2021.

Dated: August 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18587 Filed 8–27–21; 8:45 am]

BILLING CODE 4164–01–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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID 2021 DMID Omnibus BAA (HHS–NIH–NIAID–BAA2021–01) Research Area 001: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases (1).

Date: September 20, 2021.

Time: 10:00 a.m. to 5:00 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 3E72A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Frank S. De Silva, 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 3E72A, Rockville, MD 20852, (240) 669–5023, *fdesilva@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID 2021 DMID Omnibus BAA (HHS–NIH–NIAID–BAA2021–01) Research Area 001: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases (2).

Date: September 22, 2021.

Time: 10:00 a.m. to 5:00 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 3E72A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Frank S. De Silva, 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 3E72A, Rockville, MD 20852, (240) 669–5023, *fdesilva@niaid.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: August 24, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–18564 Filed 8–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Agency Emergency Information Collection Clearance Request for Public Comment

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments on the information collection request must be received on or before 10 days of this published notice.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted within 10 days. You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Office of