Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

SUPPLEMENTARY INFORMATION:

I. Background

These draft device-specific guidance documents provide performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the above-listed guidance documents, when finalized, rather than using direct predicate comparison testing for some of the performance characteristics.

These draft guidance documents are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidance documents, when finalized, will represent the current thinking of FDA on performance criteria for the Safety and Performance Based Pathway for ''Denture Base Resins'' and ''Facet Screw Systems.'' They do not establish any rights for any person and are 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* These guidance documents are also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 20001)'' or ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff (document number 21001)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidance documents contain no new collection of information, they do 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 the following FDA regulation and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions; Pre-submissions	0910–0756

Dated: August 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18592 Filed 8–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1216]

Electronic Common Technical Document; Data Standards; Specifications for Electronic Common Technical Document Validation Criteria

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing the date that FDA will begin rejecting submissions that fail either Electronic Common Technical Document (eCTD) validation 1551 or 1553, which are high severity validation errors as described in the Specifications for eCTD Validation Criteria. Validation errors 1551 and 1553 have been added to the Specifications for eCTD Validation Criteria.

DATES: Rejection for failing to pass either eCTD validation 1551 or 1553 under a submission to CDER will begin on October 18, 2021.

FOR FURTHER INFORMATION CONTACT: Jonathan Resnick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3160, Silver Spring, MD 20993–0002, 301–796–7997, *Jonathan.Resnick@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's CDER is issuing this **Federal Register** notice to announce that eCTD validations 1551 and 1553 have been added to the Specifications for eCTD Validation Criteria (available at *https://www.fda.gov/media/87056/download*) as high validation errors. Beginning October 18, 2021, FDA will reject submissions that fail either of these validations.

Under section 745A(a) (21 U.S.C. 379k–1(a)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), at least 24 months after the issuance of a final guidance document in which FDA has

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