III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14674 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1385]

Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability'' that appeared in the **Federal Register** of June 30, 2022. The document announced the publication of a draft guidance, the third in a series of four methodological patient-focused drug development guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation and International Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, email: *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, June 30, 2022 (87 FR 39101), in FR Doc. 2022–13952, the following corrections are made:

1. On page 39101, in the third column in the header of the document, ''Docket No. FDA–2018–N–2455'' is corrected to read ''Docket No. FDA–2022–D–1385.''

2. On page 39102, in first column in ''Instructions,'' ''Docket No. FDA–2018–N–2455'' is corrected to read ''Docket No. FDA–2022–D–1385.''

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14677 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2143]

Xellia Pharmaceuticals USA, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Bacitracin for Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing the approval of an abbreviated new drug application (ANDA) for bacitracin for injection, 50,000 units/vial (ANDA 203177), held by Xellia Pharmaceuticals USA, LLC (Xellia). Xellia has requested withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 11, 2022.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 301–402–9674, *Sungjoon.Chi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 31, 2020, FDA requested that all application holders of bacitracin for injection voluntarily request withdrawal of approval of their applications under § 314.150(d) (21 CFR 314.150(d)). Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug. Bacitracin for injection poses serious risks, including nephrotoxicity and anaphylactic reactions. Health care professionals generally no longer use bacitracin for injection to treat infants with pneumonia and empyema because other effective FDA-approved treatments are available that do not have these risks.

In April 2019, FDA's Antimicrobial Drugs Advisory Committee met and discussed the safety and effectiveness of bacitracin for injection. The advisory committee voted almost unanimously, with one abstention, that the benefits of bacitracin for intramuscular injection do not outweigh its risks, including nephrotoxicity and anaphylactic reactions, for the drug's only approved indication. Based on FDA's review of currently available data and information, the Agency believes that the potential problems associated with bacitracin for injection are sufficiently serious that the drug should be removed from the market.

In a letter dated June 14, 2021, Xellia requested that FDA withdraw approval of ANDA 203177 under § 314.150(d) and waived its opportunity for a hearing. Therefore, for the reasons discussed above, which the applicant does not dispute in its letter requesting withdrawal of approval under § 314.150(d), FDA's approval of ANDA 203177 and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of Xellia's bacitracin for injection (50,000 units/vial) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14680 Filed 7–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the meeting of the Biomedical Informatics, Library and Data Sciences Review Committee.

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 materials, 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: Biomedical Informatics, Library and Data Sciences Review Committee (BILDS).

Date: November 3, 2022.

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

Agenda: To review and evaluate grant applications.

Place: Video Assisted Meeting.

Contact Person: Zoe E. Huang, MD, Chief Scientific Review Officer, Scientific Review Office, Extramural Programs, National Library of Medicine, National Institutes of Health (NIH), 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, 301–594–4937, *huangz@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: July 6, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14686 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Infectious Diseases Research.

Date: August 3, 2022.

Time: 2:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiv A Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 6, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14685 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: August 4, 2022.

Time: 11:00 a.m. to 2:30 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 3G31, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Cynthia L. De La Fuente, 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 3G31, Rockville, MD 20852, 240–669–2740, *delafuentecl@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: July 5, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–14651 Filed 7–8–22; 8:45 am]

BILLING CODE 4140–01–P

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.