

individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Nominees will be selected based on expertise in the fields of pertinent disciplines involved in injury, violence, and drug overdose prevention, including, but not limited to, epidemiology, statistics, trauma surgery, rehabilitation medicine, behavioral science/psychology, health economics, program evaluation, political science, law, criminology, informatics, and other aspects of injury management. Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of BSC, NCIPC objectives (<https://www.cdc.gov/injury/bsc/>).

**DATES:** Nominations for membership on the BSC, NCIPC must be received no later than September 1, 2022. Packages received after this time will not be considered for the current membership cycle.

**ADDRESSES:** All nominations should be emailed to [ncipcbosc@cdc.gov](mailto:ncipcbosc@cdc.gov).

**FOR FURTHER INFORMATION CONTACT:** Arlene Greenspan, DrPH, MPH, PT, Associate Director for Science, NCIPC, CDC, 4770 Buford Highway NE, Mailstop S-1069, Atlanta, Georgia 30341; Telephone: (770) 488-1279; Email: [ncipcbosc@cdc.gov](mailto:ncipcbosc@cdc.gov).

**SUPPLEMENTARY INFORMATION:** The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented and the Committee's function.

Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for BSC, NCIPC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected

candidates of their appointment near the start of the term in September, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Cover letter stating area of expertise.
- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).

- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.*, CDC, NIH, FDA, SAMHSA, etc.).

Nominations may be submitted by the candidate himself or herself or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2022-14714 Filed 7-8-22; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2020-E-2120 and FDA-2020-E-2121]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; TABRECTA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TABRECTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the

Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 9, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 9, 2023. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 9, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 9, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket Nos. FDA-2020-E-2120 and FDA-2020-E-2121 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TABRECTA.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

### SUPPLEMENTARY INFORMATION:

#### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, TABRECTA (capmatinib). TABRECTA is indicated for the treatment of adult patients with metastatic non-small cell lung cancer whose tumors have a mutation that leads to mesenchymal-epithelial

transition exon 14 skipping as detected by an FDA approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for TABRECTA (U.S. Patent Nos. 7,767,675; 8,420,645) from Incyte Corp. and Incyte Holdings Corp., and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TABRECTA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

#### II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TABRECTA is 4,164 days. Of this time, 4,015 days occurred during the testing phase of the regulatory review period, while 149 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 13, 2008. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on December 13, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 10, 2019. FDA has verified the applicant’s claim that the new drug application (NDA) for TABRECTA (NDA 213591) was initially submitted on December 10, 2019.

3. *The date the application was approved:* May 6, 2020. FDA has verified the applicant’s claim that NDA 213591 was approved on May 6, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

### 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](mailto: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](mailto: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,