for PBPK models to be used for regulatory decision-making.

2. Share experiences and cases applying PBPK modeling and simulation that highlight the opportunities and limitations of this approach.

3. Obtain input from the stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making.

4. Discuss the knowledge gaps and research needs to advance PBPK modeling sciences in drug development and regulatory evaluation.

A detailed agenda will be posted in advance of the workshop at https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm.

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online by November 8, 2019, at https://www.eventbrite.com/e/pbpk-modeling-to-support-clinical-pharmacology-regulatory-decision-making-tickets-59005519096. Please provide complete contact information for each attendee.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Lauren Milligan (see FOR FURTHER INFORMATION CONTACT) no later than November 8, 2019.

Streaming Webcam of the Public Workshop: This public workshop will also be broadcast. A live broadcast of this workshop will be available at https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm on the day of the workshop. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the Federal Register, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible on https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm. It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will be available on the internet at https://www.fda.gov/Drugs/NewsEvents/ucm633778.htm.

Dated: June 6, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019–12256 Filed 6–10–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–0047]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALUNBRIG

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 ALUNBRIG and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 the SUPPLEMENTARY INFORMATION section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 12, 2019. 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 December 9, 2019. 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 August 12, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 12, 2019. 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.

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, as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–E–0047 for “Determination of Regulatory Review Period for Purposes of Patent Extension: ALUNBRIG.” 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.

• 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...
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, ALUNBRIG (brigatinib) indicated for treatment of patients with anaplastic lymphoma kinase-positive metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Subsequent to this approval, the USPTO received a patent term restoration application for ALUNBRIG (U.S. Patent No. 9,012,462) from ARIAD Pharmaceuticals, Inc. and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated February 2, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ALUNBRIG represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

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 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: June 6, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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