availability of the draft guidance of the same title. FDA received comments and considered those comments as the guidance was finalized. The final guidance clarifies the recommendations regarding eligibility criteria related to renal function, cardiac function, and hepatic function. For example, recommendations regarding the equation used to assess renal function for eligibility were clarified and recommendations regarding population pharmacokinetic analyses of patients with renal impairment were added. In addition, recommendations regarding QTc prolongation were clarified and the recommendation on patients with asymptomatic elevations in unconjugated bilirubin was removed because it is out of the scope of organ dysfunction.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies.'' It does not establish any rights for any person and is 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14996 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No.FDA–2020–N–1500]

Food and Drug Administration Hiring and Retention Interim Assessment; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is holding a virtual meeting entitled ''FDA Hiring and Retention Interim Assessment'' and an opportunity for public comment. The topic to be discussed is FDA's hiring and retention interim assessment which was an independent assessment performed by Booz Allen Hamilton, published on June 5, 2020. This public meeting will take place virtually due to extenuating circumstances and will be held by webcast only.

DATES: The public meeting will be held on July 30, 2020, from 9 a.m. to noon. Submit either electronic or written comments on this public meeting by September 30, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and 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 by September 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2020. 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 No. FDA–2020–N–1500 ''FDA Hiring and Retention Interim Assessment; Public Meeting; Request for Comments.'' 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 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Patricia Stewart, Office of Operations, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 301–796–4735, *patricia.stewart@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to share high-level findings from a recently-completed interim assessment of FDA's hiring process, conducted by a qualified, independent contractor with expertise in assessing transformation of human resources operations. FDA recognizes that the critical work to protect public health is made possible in part by the Agency's ability to attract and retain a talented, diverse, and dedicated workforce. As FDA continues to fulfil its strategic mission, it is imperative that the Agency identify and leverage the talent, skills, and diversity within—and outside of—the Agency.

These priorities are reflected in FDA's plan to enhance its hiring and retention programs; recruit qualified candidates with diverse backgrounds, experiences, and talents; provide internal development opportunities; and further enhance the Agency's ability to nurture a supportive and fair work environment. The public meeting will provide an update on FDA's progress toward PDUFA (Prescription Drug User Fee Act) and BsUFA (Biosimilar User Fee Act) user fee hiring and retention commitments and solicit input on actions with regards to the hiring process. To view the evaluation assessment report, please visit here: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report.*

This public meeting is intended to meet performance commitments included in PDUFA VI and BsUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- PDUFA VI program: *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf* and
- BsUFA II program: *https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.*

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the FDA hiring and retention programs. Booz Allen Hamilton will present their findings and recommendations that are outlined in the Interim Hiring and Retention Assessment report and FDA will provide an update on the Agency's progress in addressing the findings from the independent third-party evaluation that was published June 5, 2020. To view the evaluation assessment report, please visit here: *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-interim-hiring-and-retention-assessment-report*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://www.eventbrite.com/e/fda-hiring-and-retention-interim-assessment-public-meeting-registration-106125275556.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by July 28, 2020, 11:59 p.m. Eastern Time.

If you need special accommodations due to a disability (*e.g.* Closed Captioning), please contact Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 22, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 27, 2020. All requests to make oral presentations must be received by July 22, 2020, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Patricia Stewart (see **FOR FURTHER INFORMATION CONTACT**) no later than July 28, 2020. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is at *https://collaboration.fda.gov/fdapublicmeeting073020/.*

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 meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see A**DDRESSES**).

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–14980 Filed 7–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–4463]

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

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 XEPI 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.