TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.914; Waiver petitions	2	1	2	24	48

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate one waiver petition from each of two firms will be submitted and respondents will spend 24 hours to prepare and submit the petition to FDA.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1.908; Disclosure of sanitary specifications; operating temperature conditions.	226	1	226	0.5833 (~35 minutes)	132

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Finally, we estimate an annual third-party disclosure burden of 132 hours, assuming each of 226 firms will spend an average of 35 minutes, annually, disclosing written records as required under 21 CFR 1.908.

Based on an evaluation of the information collection, we have made no adjustments to our burden estimate.

Dated: February 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03916 Filed 2–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2252]

Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act; 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 announcing the following virtual public meeting entitled ''Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA)'' (the Program) and an opportunity for public comment. The topics to be discussed are the final assessment and public stakeholder views of the Program.

DATES: The public meeting will be held on March 22, 2022, from 9:30 a.m. to 12:30 p.m. Eastern Time and will be held by webcast only. Submit either electronic or written comments on this public meeting by May 23, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://www.eventbrite.com/e/public-meeting-on-the-final-assessment-of-the-bsufa-ii-program-tickets-229459628927.*

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 May 23, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 23, 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 No. FDA–2020–N–2252 for ''Final Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA); 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.

FOR FURTHER INFORMATION CONTACT: Kimberly Taylor, Food and Drug Administration, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1152, Silver Spring, MD 20993, 240–402–5193, *Kimberly.taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

BsUFA was originally enacted in 2012 as the Biosimilar User Fee Act under the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) for a period of 5 years. In 2017, BsUFA was renewed for 5 more years under the FDA Reauthorization Act of 2017 (FDARA) (BsUFA II) (Pub. L. 115–52, Title IV)). BsUFA was intended to provide additional revenues so that FDA can hire staff, improve systems, and continue a well-managed biosimilar biological product review process to make biosimilar biological product therapies available to patients sooner. BsUFA II was authorized to continue the collection of user fees by FDA to facilitate and expedite the process for the review of biosimilar biological products in the United States.

Under BsUFA II, FDA committed to apply a new review model to original biosimilar biologics license application (BLA) reviews. That review model is identified in section II.B. of the BsUFA II Commitment Letter as the Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs. The Program provides opportunities for increased communication between FDA and applicants, including mid-cycle and late-cycle meetings. To accommodate the increased interaction during regulatory review, FDA's review clock begins after the 60-day administrative filing review period for applications reviewed under the Program. The goal of the Program is to promote the efficiency and effectiveness of the first-cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high-quality biosimilar and interchangeable biological products.

An independent evaluator is assessing the Program to understand its effect on the review of original 351(k) BLAs. An interim assessment was published December 3, 2020, and can be accessed at *https://www.fda.gov/media/144130/download.* The BsUFA II performance commitments also call for a final assessment of the Program to be published by June 30, 2022, for public comment. The final assessment can be accessed at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-ii-assessment-program-enhanced-review-transparency-and-communication-biosimilar-user-fee-act.* A public meeting will be held on March 22, 2022, where the final assessment will be discussed, and public stakeholders may present their views on the Program.

Additional information concerning BsUFA—including the text of the law, the ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022'' (the BsUFA II Commitment Letter), ''Biosimilar Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the BsUFA Commitment Letter), key **Federal Register** documents, BsUFA-related guidances, BsUFA user fee rates, performance reports, and financial reports—may be found at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

II. Topics for Discussion at the Public Meeting

FDA and an independent contractor will discuss the findings of the final assessment, including anonymized and aggregated feedback from biosimilar BLA applicants and FDA review teams resulting from independent contractor interviews. FDA will discuss any issues identified, including any proposed plans to improve the likelihood of the Program's success. A panel of external stakeholders will also provide their perspectives.

III. Participating in the Public Meeting

Registration: Registration is optional and not required to attend this virtual public meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. If you wish to register, you can do so at *https://www.eventbrite.com/e/public-meeting-on-the-final-assessment-of-the-bsufa-ii-program-tickets-229459628927.*

Opportunity for Verbal Public Comment: Those who register online will receive a confirmation email that includes a link to a request form to make verbal public comment at the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify 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 comments and request time jointly. All requests to make a public comment during the meeting must be received by March 10, 2022, 11:59 p.m. Eastern Time. Depending on the number of requests, we will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by March 18, 2022. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: The Zoom Webinar ID for this public meeting is 161 769 1719. The webcast link for this public meeting can be found here: *https://fda.zoomgov.com/j/1617691719?pwd=dy9yRTVqdEw1dVEzTUNqelFEa3Vpdz09.* This link

should allow you to enter the webinar directly. If Zoom asks for a passcode, please use the passcode f7DLM=, which is case-sensitive.

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 **ADDRESSES**). A link to the meeting recording will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-final-assessment-program-enhanced-review-transparency-and-communication-biosimilar.*

Dated: February 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03926 Filed 2–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1311]

Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising From the COVID–19 Pandemic; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising from the COVID–19 Pandemic.'' The COVID–19 pandemic has resulted in a significant reduction in the supply of nonhuman primates (NHPs) available for conducting toxicology studies for new pharmaceuticals. This has the potential to significantly delay the development of new medications for the treatment of diseases currently without effective treatment options. This guidance provides FDA's recommendations to industry to help mitigate the NHP supply issue by reducing the demand for NHPs during the COVID–19 pandemic. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on February 24, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2021–D–1311 for ''Nonclinical Considerations for Mitigating Nonhuman Primate Supply Constraints Arising from the COVID–19 Pandemic.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.