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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sue Zuk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6684, Silver Spring, MD 20903–0002, 240–402–9133.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Microbiological Quality Considerations in Non-Sterile Drug Manufacturing.'' The guidance provides recommendations to help manufacturers assess the risk of contamination of their NSDs with objectionable microorganisms or high bioburden levels in order to establish appropriate specifications and manufacturing controls that prevent such contamination and assure the safety, quality, identity, purity, and efficacy of the NSD. The guidance also imparts specific considerations to control microbial proliferation for selected non-sterile dosage forms that may present unique manufacturing challenges and patient safety risks.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Microbiological Quality Considerations in Non-Sterile Drug Manufacturing.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139. In the **Federal Register** of July 28, 2015 (80 FR 44973), FDA published a burden analysis for preparing and maintaining CGMP records for active pharmaceutical ingredients under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)).

III. Electronic Access

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

Dated: September 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21222 Filed 9–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2316]

Benefit-Risk Assessment for New Drug and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Benefit-Risk Assessment for New Drug and Biological Products.'' FDA has developed this guidance document in accordance with commitments associated with the Prescription Drug User Fee Act of 2017 (PDUFA VI) under the FDA Reauthorization Act of 2017 and requirements under the 21st Century Cures Act (Cures Act). The intent of this guidance is to provide drug sponsors and other stakeholders with a clearer understanding of how considerations about a drug's benefits, risks, and risk management options factor into certain FDA pre- and postmarket regulatory decisions about new drug applications (NDAs) submitted under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and biologics license applications (BLAs).

DATES: Submit either electronic or written comments on the draft guidance by November 29, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2020–D–2316 for ''Benefit-Risk Assessment for New Drug and Biological Products; Draft Guidance for Industry.'' 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 draft 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 to 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, *Graham.Thompson@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Benefit-Risk Assessment for New Drug and Biological Products.'' This guidance articulates important considerations that factor into the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research's benefit-risk assessments for drug products, including how patient experience data may be used to inform benefit-risk assessment. It discusses how sponsors can inform FDA's benefit-risk assessment through the design and conduct of the development program, as well as how they may present benefit and risk information in the marketing application. It also discusses opportunities for interaction between FDA and sponsors to discuss benefit-risk considerations in connection with the development of a BLA or NDA. The guidance concludes with additional considerations on benefit-risk assessments that inform regulatory decision making that occurs in the postmarket setting.

Industry stakeholders have indicated having a clearer understanding of FDA's decision making context, and benefit-risk considerations can help inform sponsors' decisions about their drug development programs and the evidence they generate in support of their NDA or BLA. Patients and other stakeholders may gain further insight into the key issues that inform FDA's assessment of benefit and risk, and a clearer understanding of how these issues fit into the regulatory framework of drug development and evaluation.

In May 2019, FDA participated in a public meeting conducted by Duke University's Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis) on ''Characterizing FDA's Approach to Benefit-Risk Assessment Throughout the Medical Product Life Cycle'' (84 FR 17176, April 24, 2019). Materials from this meeting are available here: *https://healthpolicy.duke.edu/events/public-meeting-characterizing-fdas-approach-benefit-risk-assessment-throughout-medical.* This meeting was intended to gather industry, patient, researcher, and other stakeholder input on applying FDA's benefit-risk framework throughout the human drug lifecycle and best approaches to communicating FDA's benefit-risk assessment. This meeting was intended to meet an FDA commitment included in the sixth authorization of the PDUFA VI. Input from this meeting supported development of this draft guidance for industry.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Benefit-Risk Assessment for New Drug and Biological Products.'' 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. Additional Information

Section 3002 of Title III, Subtitle A of the Cures Act (Pub. L. 114–255), directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(8) of the Cures Act how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the FD&C Act (21 U.S.C. 355(d)), to inform regulatory decision making.

In addition, FDA committed to meet certain performance goals under the sixth authorization of PDUFA. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.2. of the commitment letter, ''Enhancing Benefit-Risk Assessment in Regulatory Decision-Making'' (available at *https://www.fda.gov/media/99140/download*), outlines work, including the

development of a draft guidance on benefit-risk assessments for new drugs and biologics, to further the Agency's implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision making, in the human drug review program.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001 as follows: (1) The content and format of investigational new drugs applications, (2) expanded access uses and treatment of patients with immediately life-threatening conditions or serious diseases or conditions, (3) regulatory requirements pertaining to postmarketing study commitments, and (4) risk evaluation and mitigation strategies pertaining to benefit-risk assessments. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 as follows: (1) The content and format of NDAs, (2) the submission of the patient population, (3) the submission of clinical trial data, and (4) benefit-risk planning, including early consultations with FDA meetings in end-of-phase 2 and pre-NDA meetings. The collections of information for good laboratory practices for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information for the submission of postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765. The collections of information in the guidance for industry entitled ''Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)'' have been approved under OMB control number 0910–0771.

IV. Electronic Access

Persons with access to the internet may obtain the draft 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: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21194 Filed 9–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0981]

Fee Rate for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for review of drug and biological products when those applications use a tropical disease priority review voucher. These vouchers are awarded to the sponsors of certain tropical disease product applications submitted after September 27, 2007, the enactment date of FDAAA, upon FDA approval of such applications. The amount of the fee submitted to FDA with applications using a tropical disease priority review voucher is determined each fiscal year based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous fiscal year and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the tropical disease priority review fee rate for FY 2022 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Andrew Bank, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62019A, Beltsville, MD, 20705–4304, 301–796–0292.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1102 of FDAAA (Pub. L. 110–85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a tropical disease (as defined in section 524(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the tropical disease product application (as defined in section 524(a)(4) of the FD&C Act), assuming other criteria are met. The recipient of a tropical disease priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262), or transfer (including by sale) the voucher to another party. The voucher may be transferred repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the PHS Act. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending upon the type of application. Information regarding the PDUFA goals is available at: *https://www.fda.gov/media/99140/download.*

The sponsor that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published guidance on its website about how this tropical disease priority review voucher program operates (available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tropical-disease-priority-review-vouchers*).

This notice establishes the tropical disease priority review fee rate for FY 2022 as $1,266,651 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2021, and will remain in effect through September 30,