ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Objective work plan	300	1	3	900	300
On-Going Progress Report	200	2	1	400	133

Estimated Total Annual Burden Hours: 433.

Authority: Section 806 [42 U.S.C. 2991d–1](a)(1) and sec. 811 [42 U.S.C. 2992].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16588 Filed 8–2–23; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1635]

Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals Under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under PEPFAR.'' The draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver under the Prescription Drug User Fee Act (PDUFA) for certain new drug applications (NDAs) for single-entity (SE) antiretroviral (ARV) and fixed-combination (FC) ARV drug products for the treatment or prevention of human immunodeficiency virus-one (HIV–1). The draft guidance is also intended to help applicants request a barrier-to-innovation waiver under those circumstances.

DATES: Submit either electronic or written comments on the draft guidance by October 2, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2018–D–1635 for ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under PEPFAR.'' 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. 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: Sophia Park, Division of User Fee Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under PEPFAR.'' This draft guidance is proposed as a revision of the guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR,'' issued February 2007. The draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver under PDUFA for certain NDAs for SE ARV and FC ARV drug products for the treatment of HIV–1. When final, this guidance will supersede the guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR,'' issued February 2007.

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 ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under PEPFAR.'' 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 FDA's guidance entitled ''Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products'' associated with requesting waivers of user fees (including PEPFAR waivers) has been approved under OMB control number 0910–0693. The collection of information in completing and submitting FDA Form FDA 3397 (Prescription Drug User Fee Coversheet) has been approved under OMB control number 0910–0297. The collection of information in 21 CFR part 314 for submission of a new drug application has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *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: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16560 Filed 8–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0001]

Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled ''Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies.'' This public meeting will satisfy the mandate of the Food and Drug Omnibus Reform Act of 2022 (FDORA) to convene a public meeting on clinical study flexibilities initiated in response to the COVID–19 pandemic. The public meeting will be convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative (CTTI) to bring the clinical research community together to discuss a variety of topics related to mitigating disruptions of clinical studies of medical products during disasters and public health emergencies (PHEs). The meeting format will include presentations and panel discussions.

DATES: The public meeting will be held virtually on October 18 and 19, 2023, from 10 a.m. to 1:30 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually using the Zoom platform. The link for the public meeting will be sent to registrants upon registration.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926, *Dat.Doan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting satisfies FDA's mandate under section 3605 of FDORA to convene a public meeting, not later than 180 days after the date when the COVID–19 emergency period ends, to discuss the recommendations provided by FDA during the COVID–19 emergency period to mitigate disruption of clinical studies. Among other things, the public meeting will include discussion about strategies for mitigating disruptions of clinical studies of medical products during disasters and PHEs.

II. Topics for Discussion at the Public Meeting

Topics for discussion during this meeting include:

1. The recommendations provided by FDA during the COVID–19 emergency period to mitigate disruption of clinical studies, including recommendations detailed in the guidance for industry, investigators, and institutional review boards entitled ''Conduct of Clinical Trials of Medical Products During the COVID–19 Public Health Emergency [1]'' (March 2020, updated August 2021)
2. The actions sponsors took to utilize such recommendations and the

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency.*