information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0880 for ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017; Draft Guidance for Industry.''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.

• 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.gpo.gov/fdsys/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.

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

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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: Keith Verrett, Division of User Fee Management and Budget Formulation Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Rm. 2179, Silver Spring, MD 20993, 301–796–7900, *CDERCollections@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017.'' GDUFA II (Pub. L. 115–52, Title III), signed into law by the President on August 18, 2017, continues FDA's and industry's goal to improve public access to safe and effective generic drugs and to improve upon the predictability of the review process. GDUFA II extends FDA's authority to collect user fees from fiscal year (FY) 2018 to FY 2022 and introduces a number of technical revisions that affect what fees are collected and how some fees are collected.

The draft guidance announced in this notice revises and replaces the draft guidance for industry on ''Assessing User Fees under the Generic Drug User Fee Amendments of 2017.'' This draft guidance addresses changes in user fee assessments from GDUFA I, user fees incurred by industry under GDUFA II, payment procedures, reconsideration and appeals, and other additional information to assist industry in complying with GDUFA II. Clarifying language was added to the revised draft guidance based on the public comments submitted for the draft guidance.

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 ''Assessing User Fees Under the Generic Drug User Fee Amendments of 2017.'' 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 draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The draft guidance refers to collections of information for filling out and submitting Form FDA 3913 (User Fee Payment Refund Request), previously approved under OMB control number 0910–0805, and Form FDA 3914 (User Fee Payment Transfer Request), previously approved under OMB control number 0910–0805.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23875 Filed 10–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4042]

Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment; 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 ''Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in all phases of development of antiviral drugs for the treatment of chronic hepatitis D virus (HDV) infection. This guidance is intended to provide consistent FDA advice to stakeholders regarding HDV drug development strategies.

DATES: Submit either electronic or written comments on the draft guidance by December 31, 2019 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–2019–D–4042 for ''Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment.'' 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.

- 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.gpo.gov/fdsys/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.

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: Aimee Hodowanec, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6341, Silver Spring, MD 20993–0002, 240–402–5752.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment.'' The purpose of this draft guidance for industry is to provide consistent recommendations for the development of antiviral drugs for the treatment of chronic HDV infection. The guidance addresses all phases of drug development, from nonclinical considerations to phase 3 trial design recommendations.

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 ''Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment.'' 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 314 for the submission of new drug applications (NDAs) has been approved under OMB control number 0910–0001. The submission of biologics license applications (BLAs) has been approved under OMB control number 0910–0338. The collection of information in 21 CFR part 312, including submissions under subpart E, has been approved under OMB control number 0910–0014. The submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The submission of medication guides under 21 CFR part 208 has been approved under OMB control number 0910–0393. The submission of prescription drug advertisements under 21 CFR 202.1 has been approved under OMB control number 0910–0686.

The collection of information in the guidance for industry entitled ''Formal Meetings between the FDA and Sponsors or Applicants of PDUFA (Prescription Drug User Fee Act) Products'' (available at *https://www.fda.gov/media/109951/download*), including requests for pre-NDA and pre-BLA meetings and other meetings, has been approved under OMB control number 0910–0429. The collection of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (available at *https://www.fda.gov/media/86377/download*),

including fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation, has been approved under OMB control number 0910–0765.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23926 Filed 10–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Office of Minority Health and Health Equity Public Meeting on Strategies To Improve Health Equity Amidst the Opioid Crisis; 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 the following public meeting entitled ''Office of Minority Health and Health Equity Public Meeting on Strategies to Improve Health Equity Amidst the Opioid Crisis.'' The purpose of this public meeting is to share information and obtain the public's perspectives on the current opioid crisis and how it specifically affects racial and ethnic minority, underrepresented, and underserved populations across the country, approaches to prevent and treat opioid use disorder, and emerging research to improve care, and explore how FDA can support those efforts.

DATES: The public meeting will be held on November 21, 2019, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Hilton Washington, DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852, 301–468–1100.

FOR FURTHER INFORMATION CONTACT: Jovonni Spinner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2384, Silver Spring, MD 20993, 301–796–8729, *Jovonni.Spinner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Minority Health and Health Equity's (OMHHE) mission is to ''promote and protect the health of diverse populations through research and communication that addresses health disparities.'' Racial and ethnic minorities have experienced an increase in opioid-involved overdose deaths over the past few years. For example, the rate of opioid-involved overdose death nearly doubled among Black/non-Hispanic populations between 2015 (6.6 per 100,000 population) and 2017 (12.9 per 100,000 population) (Ref. 1). It has also been shown that racial and ethnic minority populations suffer from chronic pain at higher rates than other populations and the evaluation and treatment for pain management may vary across ethnic groups (Ref. 2). The opioid crisis is a multifaceted issue and our aim is to convene diverse stakeholders to stimulate dialogue that will highlight and bring about solutions to improve the health of the communities we serve. Meeting discussions will inform future programming for the OMHHE.

II. 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-omhhe-strategies-to-improve-health-equity-amidst-the-opioid-epidemic-tickets-70822278341.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Anonymous registration is available. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time, November 15, 2019. Early registration is recommended because seating is limited; therefore, 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 meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Jovonni Spinner at 301–796–8729 or *Jovonni.Spinner@fda.hhs.gov* no later than November 7, 2019.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast: *https://www.eventbrite.com/e/fda-omhhe-strategies-to-improve-health-equity-amidst-the-opioid-epidemic-tickets-70822278341.*

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Henry, J., Kaiser Foundation, ''Opioid Overdose Deaths by Race/Ethnicity.'' Available at: *https://www.kff.org/other/state-indicator/opioid-overdose-deaths-by-raceethnicity/?dataView=2&activeTab=graph&currentTimeframe=0&startTimeframe=18&selectedDistributions=white-non-hispanic--black-non-hispanic-hispanic&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.* Accessed on September 9, 2019.

2. Campbell, C.M. and R.R. Edwards, ''Ethnic Differences in Pain and Pain Management.'' *Pain Management,* vol. 2(3), pp. 219–230, 2012.*

Dated: October 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23941 Filed 10–31–19; 8:45 am]

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