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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under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 This draft guidance is proposed as a revision of the guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR,'' issued February 2007. The draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver under PDUFA for certain NDAs for SE ARV and FC ARV drug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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of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.*

frequency at which such recommendations were utilized

3. The characteristics of the sponsors, studies, and patient populations impacted by such recommendations
4. Consideration of how recommendations intended to mitigate disruption of clinical studies during the COVID–19 emergency period, including any recommendations to consider decentralized clinical studies when appropriate, may have affected access to clinical studies for certain patient populations, especially underrepresented racial and ethnic minorities
5. Recommendations for incorporating certain clinical study disruption mitigation recommendations into current or additional guidance to improve clinical study access and enrollment of diverse patient populations
6. Strategies for advanced planning to mitigate disruption of clinical studies during future disasters and PHEs

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *duke.zoom.us/meeting/register/tJAvcO-oqD4vE9Ov1Vv-A3SoItVhL7Rhg66T.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free, and persons interested in attending this public meeting must register to receive a link to the meeting. Registrants will receive a confirmation email after they register.

If you need special accommodations due to a disability, please contact *Summer.Starling@duke.edu* no later than October 4, 2023. Please note, closed captioning will be available automatically.

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16544 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–P–2339]

Determination That K–TAB (Potassium Chloride) Extended-Release Tablets, 10 Milliequivalents and 20 Milliequivalents, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that K–TAB (potassium chloride) extended-release tablets, 10 milliequivalents and 20 milliequivalents, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for potassium chloride extended-release tablets, 10 milliequivalents (meqs) and 20 meqs, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Veniqua Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3627, *veniqua.stewart@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, are two of the subjects of NDA 018279, held by AbbVie Inc. The NDA was initially approved on June 9, 1980. K–TAB is indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.

The K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Granules India Ltd. submitted a citizen petition dated June 8, 2023 (Docket No. FDA–2023–P–2339), under 21 CFR 10.30, requesting that the Agency determine whether K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of K–TAB (potassium chloride) extended-release tablets, 10 meqs and 20 meqs, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list K–TAB (potassium