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That K–TAB (Potassium Chloride) Extended-Release Tablets, 10 Milliequivalents and 20 Milliequivalents, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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that K–TAB (potassium chloride) extended-release tablets, 10 milliequivalents and 20 milliequivalents, were not withdrawn from sale for reasons of safety or effectiveness.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

chloride) extended-release tablets, 10 meqs and 20 meqs, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16537 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–2004–D–0301]

Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of Human Immunodeficiency Virus-One 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 ''Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of HIV–1 Under PEPFAR.'' This draft guidance provides recommendations for applications for single-entity antiretroviral (ARV) and ARV fixed-combination (FC) drug products for the treatment or prevention of human immunodeficiency virus-one (HIV–1) infection that are intended for procurement under the President's Emergency Plan for AIDS Relief (PEPFAR). Specifically, this draft guidance addresses versions of ARV drug products for which the individual ARV drug product components are already FDA-approved and for which substantial evidence of safety and efficacy of the specific drug product or combination drug product already exists. When finalized, this draft guidance will replace the previous final guidance for industry entitled ''Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV'' issued in October 2006.

DATES: Submit either electronic or written comments on the draft guidance by November 1, 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–2004–D–0301 for ''Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV–1 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