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of Human Immunodeficiency Virus-One Under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of HIV–1 Under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 This draft guidance provides recommendations for applications for single-entity antiretroviral (ARV) and ARV fixed-combination (FC) drug products for the treatment or prevention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 Specifically, this draft guidance addresses versions of ARV drug products for which the individual ARV drug product components are already FDA-approved and for which substantial evidence of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 When finalized, this draft guidance will replace the previous final guidance for industry entitled ''Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously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DATES: Submit either electronic or written comments on the draft guidance by November 1, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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

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: Sarita Boyd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 ARV and ARV FC drug products for the treatment of HIV–1 infection that are intended for procurement under 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. The draft guidance discusses regulatory procedures relevant to such applications and recommendations on how to identify and address common issues. The recommendations in this draft guidance primarily focus on the tentative approval of marketing applications intended for procurement under PEPFAR, where there are patent or exclusivity barriers to final marketing approval.

When finalized, this draft guidance will replace the previous final guidance for industry entitled ''Fixed Dose Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV,'' issued October 18, 2006 (71 FR 61483). Important changes in this draft guidance compared to the 2006 final version include the following:

- Addition of information about ARV drug products for prevention of HIV–1 infection.
- Deletion of references to co-packaged products and focus on single-entity ARV and ARV FC drug products currently most needed under PEPFAR.
- Inclusion of a subsection that describes the processes for making changes to applications after tentative approval.
- Addition of updated descriptions of regulatory requirements and procedures in the main text of the document and deletion of Attachments A, B, and C.
- Addition of updated information, for example, in the section on chemistry, manufacturing, and controls, to be consistent with other guidances for industry released after 2006.

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 ''Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of HIV–1 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 draft 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 312 for the submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for the submission of new drug applications, abbreviated new drug applications and supplemental applications have been approved under OMB control number 0910–0001. The collections of information for the submission of controlled correspondence related to generic drug development have been approved under OMB control number 0910–0797. The collections of information pertaining to Prescription Drug User Fee Program have been approved under OMB control number 0910–0297. The collections of information pertaining to Generic Drug User Fee Program have been approved under 0910–0727. The collections of information related to expedited review programs for serious conditions have been approved under OMB control number 0910–0765. 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 parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 201.57 for the submission of prescription drug product labeling have been approved under OMB control number 0910–0572. The collections of information pertaining to good clinical practice have been approved under OMB control number 0910–0843.

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. 2023–16557 Filed 8–2–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 5, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0520. Also include the FDA docket number found in brackets in the heading of this document.