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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment or Prevention of HIV–1 Under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 This draft guidance provides recommendations for applications for single-entity ARV and ARV FC drug products for the treatment of HIV–1 infection that are intended for procurement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 Specifically, this draft guidance addresses versions of ARV drug products for which the individual ARV drug product components are already FDA-approved and for which substantial evidence of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 The draft guidance discusses regulatory procedures relevant to such applications and recommendations on how to identify and address common issues. The recommendations in this draft guidance primarily focus on the tentative approval of marketing applications intended for procurement under PEPFAR, where there are patent or exclusivity barriers to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When finalized, this draft guidance will replace the previous final guidance for industry entitled ''Fixed Dose Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for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 Important changes in this draft guidance compared to the 2006 final version include the following: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]

BILLING CODE 4164–01–P

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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.'' Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain specific information that indicates prior refusals by any country and identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers.

This information collection enables FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *https://www.access.fda.gov.* Information the Agency collects in the prior notice submission includes: (1) the submitter and transmitter (if different from the submitter); (2) entry type and CBP identifier; (3) the article of food, including complete FDA product code; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper, except for food imported by international mail; (9) the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, except for food imported by international mail; and (13) planned shipment information, except for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACE at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACE in column 6 entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under § 801(l) of the FD&C Act, § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

In the **Federal Register** of February 27, 2023 (88 FR 12366), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions:						
Through ABI/ACE.						
1.280 through 1.281	N/A	1,900	7,895	15,000,500	0.167 (10 minutes).	[2] 2,505,084
Through PNSI.						

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.280 through 1.281	[3] 3540	13,000	231	3,003,000	0.384 (23 minutes).	1,153,152
Subtotal						3,658,236
Cancellations:						
Through ABI/ACE.						
1.282	N/A	25,000	1	25,000	0.25 (15 minutes).	6,250
Through PNSI.						
1.282 and 1.283(a)(5)	3540	50,000	1	50,000	0.25 (15 minutes).	12,500
Subtotal						18,750
Requests for Review and Post-hold Submissions:						
1.283(d) and 1.285(j)	N/A	1	1	1	8	8
1.285(i)	N/A	500	1	500	1	500
Subtotal:						508
Total				18,079,001		3,677,494

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double counting, an estimated 396,416 burden hours already accounted for in the importer's entry notice information collection approved under OMB control number 0910–0046 are not included in the total.
[3] The term "Form FDA 3540" refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Table 1 reflects the annual estimated reporting burden associated with the information collection. During the next 3 years, we estimate each respondent will need approximately 10 minutes per submission for a total of 15,000,500 annual submissions and 2,505,083.5 rounded up to 2,505,084 annual hours of burden. Similarly, we estimate 13,000 users submitting an average of 231 notices annually, requiring approximately 23 minutes per submission. Cumulatively, this totals 3,003,000 annual responses and 1,153,152 annual hours of burden.

Regarding cancellations of prior notices, we estimate 25,000 respondents averaging 1 cancellation annually and requiring 15 minutes to do so. Cumulatively, this totals 25,000 annual submissions and 6,250 annual hours of burden. Similarly, we estimate 50,000 registered users submitting an average of 1 cancellation annually and requiring 15 minutes to do so. Cumulatively, this totals 50,000 annual responses and 12,500 annual hours of burden.

We estimate that we will receive one submission annually under § 1.283(d) or § 1.285(j) over the next 3 years. It takes approximately 8 hours to prepare a submission, which results in 8 hours of burden.

Finally, for an average of 500 post-hold submissions annually, we estimate it will take respondents 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total of 500 annual burden hours.

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we are adjusting our burden estimate for this information collection by increasing the number of responses and total burden. The number of responses has increased by 3,146,589 responses (from 14,932,412 to 18,079,001). The total burden has increased by 769,918 hours (from 2,907,576 to 3,677,494). We attribute the adjustment to an increase in the number of responses.

Dated: July 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16568 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–2022–N–2175]

Raidel Figueroa: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Raidel Figueroa from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Figueroa was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Figueroa was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Figueroa has not responded to the notice. Mr. Figueroa's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 3, 2023.

ADDRESSES: Any application by Mr. Figueroa for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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