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

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 356V	187	36.5	6,825	0.75 (45 minutes)	5,118
VMF submissions	15	1	15	20	300
Total			7,628		38,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Although we have characterized the information collection activity as a reporting burden, we include in our estimate time required for searching data sources, and preparing and maintaining necessary and applicable records. As stated above, although we receive fewer than one submission annually when averaged over a 3-year period, we attribute one response and 1 hour annually to account for CNADA submissions

We have adjusted our estimate of the information collection to reflect a decrease in burden associated with application submissions in acknowledgement of respondents' preference in using FDA's ''eSubmitter'' system, which automatically generates Form FDA 356v and allows respondents to complete the form and submit applications and associated information electronically.

Dated: February 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04373 Filed 3–1–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0836]

Pre-Launch Activities Importation Requests; 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 final guidance for industry entitled ''Pre-Launch Activities Importation Requests (PLAIR).'' This guidance finalizes and updates the draft guidance of the same title issued on July 24, 2013. This guidance finalizes FDA's approach for overseeing requests regarding the importation of unapproved finished dosage form drug products by applicants preparing products for market launch based on anticipated approval of a pending new drug application (NDA) or an abbreviated new drug application (ANDA). This guidance also applies to biologics licensing applications (BLAs) regulated by the Center for Drug Evaluation and Research. This guidance further describes the procedures for making these requests and FDA's actions on such requests. Finalizing this policy will help increase efficiencies in ensuring timely access to drug products upon approval.

DATES: The announcement of the guidance is published in the **Federal Register** on March 2, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2013–D–0836 for ''Pre-Launch Activities Importation Requests (PLAIR).'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Kathleen Joyce, Center for Drug Evaluation and Research, Bldg. 51, Rm. 4236, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *Kathleen.Joyce@fda.hhs.gov,* or PLAIR Program, Office of Drug Security, Integrity and Recalls (ODSIR), *CDER-OC-PLAIR@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pre-Launch Activities Importation Requests (PLAIR).'' Historically, when applicants with a pending NDA, ANDA, or CDER-regulated BLA sought to import unapproved finished dosage form drug products into the United States in preparation for market launch, we considered such requests, informally referred to as ''PLAIRs,'' on a case-by-case basis. In July 2013, FDA issued a draft guidance announcing the Agency's approach for overseeing the import of some unapproved finished dosage form drug products regulated by CDER prior to their approval to facilitate the availability of those products to patients upon approval. This guidance largely tracks the July 2013 draft guidance.

An applicant with a pending NDA, ANDA, or BLA that is nearing an FDA decision may submit a PLAIR to FDA seeking permission to import the unapproved finished dosage form drug product that is the subject of the application to prepare the product for market launch. If FDA grants the PLAIR, FDA intends to detain the unapproved finished dosage form drug product when the product covered by the PLAIR is offered for import. FDA will, however, consider the PLAIR submission to mean that the owner or consignee has requested to recondition the drug, as specified in the PLAIR request. FDA will thus detain the drug for up to 6 months pending a decision on the underlying application. The Agency will release the drug product if, and when, FDA approves the underlying NDA, BLA, or ANDA within 6 months and the conditions of the PLAIR are otherwise met. If FDA refuses to approve the application or 6 months otherwise elapse without FDA approval, FDA may determine that the product is subject to refusal.

FDA's granting of a PLAIR does not represent an implicit or explicit statement of the approvability of the application. Rather, PLAIR facilitates the process of importing unapproved finished dosage form products to prepare for market launch based on the anticipated approval by FDA of the pending application. The PLAIR guidance outlines which products the PLAIR program covers, what information should be submitted to FDA in a PLAIR, when and how we recommend submitting a PLAIR, and the process for FDA's action on a PLAIR.

FDA considered comments received on the draft guidance as the guidance was finalized. One change we made in response to comments was to include recommended timeframes for earlier submission of certain PLAIR-eligible products subject to priority review.

This guidance finalizes the draft guidance entitled ''Pre-Launch Activities Importation Requests (PLAIR)'' issued on July 24, 2013 (78 FR 44572) and is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Pre-Launch Activities Importation Requests (PLAIR).'' 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 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. 3501–3521). The time required to complete this information collection is estimated to average 16 hours for the first submission, including the time to review instructions. We expect any additional PLAIRs submitted by the same firm to take less time. The collections of information pertaining to FDA's Pre-Launch Activities Importation Requests have been approved under OMB control number 0910–0046. The guidance also refers to other previously approved FDA collections of information. The collections of information in 21 CFR part 314 relating to new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001; the collections of information in part 601 relating to biologics license applications have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 207 relating to domestic and foreign facility registration, including assignment of a national drug code, have been approved under OMB control number 0910–0045; and the collections of information in parts 210 and 211 pertaining to current good manufacturing practice requirements have been have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *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: February 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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