DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0836]

Draft Guidance for Industry on Pre-Launch Activities Importation Requests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pre-Launch Activities Importation Requests (PLAIR).'' This draft guidance describes FDA's policy regarding requests for the importation of unapproved finished dosage form drug products by applicants preparing products for market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 This draft guidance also applies to biologics licensing applications (BLAs) regulated by the Center for Drug Evaluation and Research. This draft guidance further describes the procedures for making these requests and the criteria that FDA will consider in granting such requests.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 23, 2013. Submit either electronic or written comments concerning the proposed collection of information by September 23, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marybet Lopez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4286, Silver Spring, MD 20993–0002, 301–796–3110; or Stella Notzon, Office of Regulatory Affairs, Division of Import Operations, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–6678.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pre-Launch Activities Importation Requests (PLAIR).'' Historically, when applicants sought to import unapproved finished dosage form drug products in preparation for market launch, FDA considered such requests, informally referred to as PLAIRs, on a case-by-case basis. FDA has decided to create a more formal program, and this guidance outlines what information should be submitted to FDA in a PLAIR, when and how a PLAIR can be submitted, and the circumstances under which the Agency intends to grant a PLAIR.

An applicant who has an NDA, ANDA, or a BLA pending that is nearing an FDA application decision can submit a PLAIR request to FDA regarding the importation of 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 request, when the product is then offered for import, FDA intends to detain the unapproved finished dosage form drug product. FDA will, however, regard the PLAIR request to mean that the owner or consignee has requested to recondition the drug, as specified in the PLAIR request FDA has granted. 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 when and if FDA approves the underlying NDA or ANDA within 6 months and the conditions of the PLAIR are otherwise met.

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 Agency's current thinking on PLAIRs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Pre-Launch Activities Importation Requests (PLAIR).

Description: The draft guidance outlines what information should be submitted to FDA in a PLAIR, when and how a PLAIR can be submitted, and the circumstances under which the Agency intends to grant a PLAIR. Section III of the draft guidance requests information collection that is subject to the PRA, including the information that should be included in a PLAIR, the information to be submitted to the Office of Regulatory Affairs (ORA)/Division of Import Operations (DIO) following FDA granting a PLAIR, and the notification to ORA/DIO after the applicant receives notice from FDA that its drug product is approved. Based on FDA's experience with informal requests by applicants to import unapproved drug products for purposes described in the draft guidance, we estimate that approximately 184 PLAIRs from approximately 50 applicants will be submitted annually, and that it will take applicants approximately 16 hours to prepare and submit each PLAIR. This burden estimate also includes the time

for submitting the information described above to ORA/DIO.

FDA requests comments on this information collection:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PLAIR	50	3.68	184	16	2,944

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any additional information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0755]

Guidance for Industry on Providing Submissions in Electronic Format—Postmarket Non-Expedited Individual Case Safety Reports; Technical Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance to industry entitled ''Providing Submissions in Electronic Format—Postmarket Non-Expedited ICSRs; Technical Questions and Answers.'' The guidance provides firms with information on the appropriate electronic file format to use when electronically submitting to FDA postmarket non-expedited individual case safety reports (ICSRs) on adverse drug experiences.[1] The guidance explains that firms that had previously submitted non-expedited ICSRs in an electronic format that is not supported by FDA should contact the Center for Drug Evaluation and Research (CDER) or Center for Biologics and Evaluation and Research (CBER) and resubmit their non-expedited ICSRs in a compatible electronic format.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFD–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jeffrey Trunzo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4447, Silver Spring, MD 20993–0002, 301–796–2029, email: *jeffrey.trunzo@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Providing Submissions in Electronic Format—Postmarket Non-Expedited ICSRs; Technical Questions and Answers.'' The guidance provides firms with information on the appropriate electronic file format to use when electronically submitting to FDA postmarket non-expedited ICSRs for adverse drug experiences. The guidance explains that firms that had previously submitted non-expedited ICSRs in an electronic format that is not supported by FDA should contact CDER or CBER and resubmit their non-expedited ICSRs in a compatible electronic format.

FDA regulations at §§ 314.80(c)(2) and 600.80(c)(2) (21 CFR 314.80(c)(2) and 600.80(c)(2)) require applicants to submit postmarket periodic safety reports at prescribed intervals. Each periodic safety report must contain a descriptive portion and the non-expedited ICSRs [2] for the reporting interval. The descriptive portion can be submitted as a periodic adverse drug experience report [3]; a periodic adverse experience report [4]; a periodic safety

[1] For purposes of this guidance, *adverse drug experience* includes an adverse experience associated with use of a drug or biological product, including a therapeutic vaccine.

[2] As described in §§ 314.80(c)(2)(ii)(*b*) and 600.80(c)(2)(ii)(B). Non-expedited ICSRs were previously referred to as *periodic ICSRs.*

[3] *As described in* § 314.80.

[4] A*s described in* § 600.80.