DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–R–53]

Agency Information Collection Activities: Submission for OMB Review

ACTION: Notice; withdrawal.

SUMMARY: The Centers for Medicare and Medicaid Services published a document in the **Federal Register** on January 27, 2014, concerning the submission of an information collection request for OMB review and a request for public comments. The document was published in error.

Withdrawal

In the **Federal Register** of January 27, 2014, in FR Doc. 2014–01465, on page 4345 in the second and third columns and on page 4346 in the first column, a 30-day notice for an information collection request published. We are withdrawing the notice and thereby the information collection request (ICR). At this time, we are not submitting the ICR to OMB and we are not requesting public comments. The collection is entitled, ''Imposition of Cost Sharing Charges Under Medicaid and Supporting Regulations.''

Dated: February 4, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–02660 Filed 2–6–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0077 (formerly 2007D–0213)]

Guidance for Industry; Providing Regulatory Submissions in Electronic Format—Receipt Date; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Receipt Date.'' This guidance describes how FDA will assign receipt dates to certain submissions provided in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This document finalizes the guidance of the same name, which was issued in June 2007.

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

ADDRESSES: Submit written requests for single copies of the documents 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 the 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 documents.

Submit electronic comments on the 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: Edward Hallissey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301–796–0420; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 5515 Security Lane, Rm. 5130, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Receipt Date.'' This guidance describes how FDA will assign receipt dates to certain submissions provided in electronic format or in physical media to CDER and CBER.

When CDER or CBER receives a submission, the receipt date may be used to determine important regulatory milestones, such as FDA's 30-day safety review cycle for an investigative new drug (IND) application. The guidance provides clarity regarding when items submitted electronically are deemed received by FDA for purposes of such milestones. Prior to issuance of this final guidance, certain submissions received through the electronic submission gateway (ESG) after 4:30 p.m. were deemed to be received on the following business day. With this final guidance, we are generally eliminating this 4:30 p.m. cut-off for submissions received through the ESG Monday through Friday. However, certain submissions received through the ESG on a weekend, Federal holiday, or on a day when the FDA office that will review the submission is otherwise not open for business, will be assigned a receipt date corresponding to the next business day.

Occasionally, submissions in electronic format have technical deficiencies that prevent FDA from opening, processing, or archiving the submission. The guidance explains that FDA considers a technically deficient electronic submission to be not received (i.e., not present at the Agency and not under review) until all technical deficiencies are resolved.

On June 5, 2007 (72 FR 31079), FDA announced the availability of the draft version of this guidance. The public comment period closed on August 6, 2007. Several comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. Those changes clarified the draft guidance and updated the document to reflect legislative provisions adopted since the draft was issued. More specifically, the final guidance generally eliminates the 4:30 p.m. cut-off for submissions received through the ESG Monday through Friday. It also provides guidance on FDA's interpretation of a provision in the Generic Drug User Fee Amendments of 2012 (GDUFA) concerning the date of submission for Type II drug master files, Abbreviated New Drug Applications (ANDAs), and amendments and supplements to ANDAs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on determining the receipt date for certain submissions in electronic format or in physical media. 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. Paperwork Reduction Act of 1995

The guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. The guidance pertains to sponsors and applicants making regulatory

submissions to FDA in electronic format for INDs, pre-market applications, including new drug applications (NDAs), ANDAs, biologics license applications (BLAs), and amendments and supplements to these applications, master files (MFs), postapproval studies (whether submitted as supplements to approved applications or otherwise), submissions related to products marketed without an approved application, and adverse event reports. The information collection discussed in the guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document 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/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02654 Filed 2–6–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0967]

Pulmonary Arterial Hypertension Public Meeting on Patient-Focused Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for pulmonary arterial hypertension. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of pulmonary arterial hypertension on daily life, as well as their perspectives on the available therapies for pulmonary arterial hypertension.

DATES: The public meeting will be held on May 13, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by April 30, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by July 14, 2014.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm379694.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1199, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, email: *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected pulmonary arterial hypertension as the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 21613) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FYs) 2013 through 2015, the first 3 years of the 5-year PDUFA V time frame. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 58849), and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FYs 2016 through 2017. More information, including the list of disease areas and a general