used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 15 requests for revision of the regulatory review period have been submitted under § 60.24(a). For 2010, 2011, and 2012, a total of three requests have been submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

In the **Federal Register** of November 14, 2013 (78 FR 68454), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24(a)	1	1	1	100	100
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total					160

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

Dated: February 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02753 Filed 2–7–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0039 (Formerly 2006D–0408)]

Annual Reports for Approved Premarket Approval Applications, Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Annual Reports for Approved Premarket Approval Applications (PMA).'' The purpose of this guidance is to describe the information required to be included in an annual report for an approved PMA, additional information requirements that may be imposed by an approval order, and FDA's recommendations for the level of detail the applicant should provide in the annual report. It also identifies the steps FDA staff generally takes when reviewing annual reports, the resources available to assist staff in their reviews, and the regulatory actions they may recommend after reviewing annual reports.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Annual Reports for Approved Premarket Approval Applications (PMA)'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), 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 request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570; 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.

I. Background

In the **Federal Register** of October 26, 2006 (71 FR 62595), FDA announced the availability of its draft guidance entitled, ''Annual Reports for Approved Premarket Approval Applications (PMA),'' and invited interested persons to comment on the document. FDA received several comments, most of which sought additional clarification and recommendations about the level of detail and format of annual reports. We

considered all of the comments received and revised the guidance where appropriate.

II. Significance of Guidance

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 annual reports for PMAs. 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all Center for Device and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov* or from the Center for Biologics Evaluation and Research (CBER) at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Annual Reports for Approved Premarket Approval Applications (PMA),'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1585 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR 814.82(a)(7) and 814.84(b) have been approved under OMB control number 0910–0231.

Under section 3506(c)(2)(A) of the PRA, FDA provided a 60-day notice concerning the proposed collection of information set forth in the draft guidance (71 FR 62595, October 26, 2006). In response to the notice, FDA received several comments pertaining to the information collection.

Comments noted that for changes previously submitted in a regulatory submission, requiring a rationale for each change is burdensome and duplicative because FDA already has this information. In response to this comment, FDA modified the guidance to request only limited information for changes that were submitted as either a PMA supplement or 30-day notice, including supplement number and the status of the document.

Comments requested clarification of the type of information, data, and level of detail that need to be provided. In response, FDA removed columns from the proposed ''Changes Table'' in the guidance, including columns for validation testing, implementation date, approval date, and risk analysis.

As a result of modifications made to the guidance in response to comments, the guidance no longer imposes an information collection burden additional to that previously approved in OMB control number 0910–0231. FDA is therefore no longer requesting approval of an additional information collection.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. It is necessary to send only 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*.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02765 Filed 2–7–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0128] (Formerly Docket No. 2007D–0396)

Serious Drug-Induced Liver Injury: Who Gets It? Who Doesn't? Why?; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled ''Serious Drug-Induced Liver Injury (DILI): Who Gets It? Who Doesn't? Why?'' This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. Its purpose is to discuss, debate, and share views among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 19, 2014, from 8 a.m. to 6 p.m., and March 20, 2014, from 8 a.m. to 4 p.m.

ADDRESSES: The conference will take place at the College Park Marriott Hotel & Conference Center, 3501 University Blvd., Hyattsville, MD 20783. The hotel's phone number is 301–985–7300.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4482, Silver Spring, MD 20993–0002, 301–796–0518, *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of guidance for industry entitled ''Drug-Induced Liver Injury: Premarketing Clinical Evaluation'' (74 FR 38035; July 30, 2009). This guidance explained that DILI was the most frequent cause of safety-related drug marketing withdrawals for the past 50 years and that hepatotoxicity has limited use of many drugs that have been approved and prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration, and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. It suggests some ''stopping rules'' for interrupting drug treatment, and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009. FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.