DATES: Submit either electronic or written comments on the collection of information by November 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information 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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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, including each proposed extension of an existing 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 comments 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 of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for Participation in the Medical Device Fellowship Program—(OMB Control Number 0910–0551)—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. Collecting applications for the Medical Device Fellowship Program will allow FDA's Center for Devices and Radiological Health (CDRH) to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application Form (Form FDA 3608)	250	1	250	1	250

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

Dated: September 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21893 Filed 9–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0880]

Draft Guidance for Industry on Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1); 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 ''Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1).'' The Generic Drug User Fee Amendments of 2012 (GDUFA) is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program. GDUFA also requires that generic drug facilities, sites, and organizations located around the world provide identification information annually to FDA. This guidance is intended to provide updated answers to common questions from the generic drug industry and other interested parties involved in the development and/or testing of generic drug products regarding the requirements and commitments of GDUFA.

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 November 12, 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: Jaewon Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., rm. 4145, Silver Spring, MD 20993, 301–796–6707, *Ask GDUFA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

GDUFA (Pub. L. 112–144, Title III) was signed into law by the President on July 9, 2012. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

GDUFA establishes fees for abbreviated new drug applications (ANDAs), prior approval supplements (PASs) to ANDAs, and drug master files (DMFs), annual facility fees, and a one-time fee for original ANDAs pending with FDA on October 1, 2012 (backlog fees). Fees are incurred for ANDAs and PASs submitted on or after October 1, 2012. An application fee is also incurred the first time a DMF is referenced in an ANDA or PAS submitted on or after October 1, 2012. FDA previously announced GDUFA fees for fiscal year 2013 in the **Federal Register.** ANDA, PAS, and DMF fees were published on October 25, 2012 (77 FR 65198); the backlog fee was published on October 25, 2012 (77 FR 65199); and facility fees were published on January 17, 2013 (78 FR 3900). GDUFA fees for fiscal year 2014 were announced in the **Federal Register** of August 2, 2013 (78 FR 46977).

On August 27, 2012, FDA announced the availability of a draft guidance for industry entitled ''Generic Drug User Fee Amendments of 2012: Questions and Answers'' (77 FR 51814). The comment period on the draft guidance closed on October 26, 2012. In response to comments received in the docket and to address additional questions that have arisen since the launch of the GDUFA program, FDA has revised the draft guidance and is issuing it again in draft to solicit public comment. Revision 1 clarifies some of the questions and answers in the first version and adds several new questions and answers. The questions and answers address four key categories: Fees; self-identification of facilities, sites, and organizations; review of generic drug submissions; and inspections and compliance.

This revised 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 ''Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1).'' 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. 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.*

III. 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: September 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–21891 Filed 9–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0503]

Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for clinical investigators, sponsors, and institutional review boards (IRBs) entitled ''Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.'' The guidance is intended to assist clinical investigators, sponsors, sponsor-investigators, and IRBs in determining whether human research studies must be conducted under an IND. The guidance describes the basic criteria for determining when an IND is required, describes specific situations in which an IND is not required, and addresses a range of issues that, in FDA's experience, have been the source of confusion or misperceptions about the application of the IND regulations.

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 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; or Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. 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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Peter Taschenberger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2211, Silver Spring, MD 20993–0002, 301–796–2500, 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, or David Hattan, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1293.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for clinical investigators, sponsors, and IRBs entitled