otherwise support the generic drug program. A copy of the proposed form will be available in the docket for this notice.

Respondents to this proposed collection of information would be potential or actual generic application holders and/or related manufacturers (manufacturers of FDF and/or APIs). Companies with multiple applications will submit a cover sheet for each application and facility. Based on FDA's database of application holders and related manufacturers, we estimate that 500 companies would submit a total of 3,850 cover sheets annually to pay for application and facility user fees. FDA estimates that the 3,850 annual cover sheet responses would break down as follows: [1] 2,000 facilities fees, 750 ANDAs, 750 PASs, and 350 Type II API DMFs. We also estimate that the one-time backlog fee would affect 350 application owners sponsoring 2,700 applications. The estimated hours per response are based on FDA's past experience with other submissions, and range from approximately 0.1 to 0.5 hours. The hours per response are estimated at the upper end of the range to be conservative.

In the **Federal Register** of July 26, 2012 (77 FR 43844), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received the following comment. Small generic manufacturers will heavily suffer from the establishment fees under GDUFA. FDA notes this comment is outside the scope of the proposed collection of information, Form FDA 3794 (Generic Drug User Fee Cover Sheet).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794 [2]	500	7.7	3,850	0.5	1,925

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For all applicable applications and fees except for the backlog fee.

The backlog fee is a one-time fee. The Agency expects the majority of these fees to be received in the first year only. The estimated reporting burden for the backlog fee is shown in table 2 of this document.

TABLE 2—ESTIMATED ONE-TIME ANNUAL REPORTING BURDEN [1]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3794 [2]	350	7.7	2,700	0.5	1,350

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

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27003 Filed 11–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0433; (formerly Docket No. 2007D–0169)]

Draft Guidance for Industry on Bioequivalence Recommendation for Lenalidomide Capsules; 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 ''Draft Guidance on Lenalidomide.'' The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for lenalidomide capsules. The draft guidance is a revised version of a previously published draft guidance on the subject.

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 the draft guidance before it begins work on the final versions of the guidance, submit either electronic or written comments on the draft guidance by January 7, 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: Kris Andre, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make

[1] These estimates are based on conversations between the Agency and representatives of regulated industry during the generic drug user fee negotiations.

product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for lenalidomide capsules.

Revlimid (lenalidomide capsules), approved by FDA on December 27, 2005, is a thalidomide analogue indicated for the treatment of: Multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy and also in patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. Revlimid is designated as the reference listed drug, and therefore any ANDAs for generic lenalidomide capsules must demonstrate BE to the Revlimid prior to approval. There are no approved ANDAs for this product.

In June 2010, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for lenalidomide capsules. In that draft guidance, FDA recommended studies in the 15 milligram (mg) and 25 mg strengths of lenalidomide capsules to demonstrate BE. FDA has now determined that a BE study in the 15 mg strength is unnecessary and is revising the guidance to remove that recommendation. FDA also is revising the guidance to recommend that a request for a waiver of in vivo testing be submitted for the 2.5 mg, 5 mg, 10 mg, and 15 mg strengths based on: (1) Acceptable fasting and fed bioequivalence studies on the 25 mg strength, (2) proportional similarity of the formulations across all strengths, and (3) acceptable in vitro dissolution testing of all strengths.

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 the design of BE studies to support ANDAs for lenalidomide capsules. They do not create or confer any rights for or on any person and do 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 written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov*. 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 documents at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27004 Filed 11–5–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: National Database for Autism Research (NDAR) Data Access Request

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act (PRA) of 1995, the National Institute of Mental Health (NIMH), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 22, 2012, page 37683–37684 (2 pages) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: National Database for Autism Research (NDAR) Data Access Request. *Type of Information Collection Request:* 0925–NEW. *Need and Use of Information Collection:* The NDAR Data Access Request form is necessary for ''Recipient'' Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the NDAR Central Repository for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the NDAR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. *Frequency of Response:* Once per request. *Affected Public:* Individuals. *Type of Respondents:* Researchers interested in obtaining access to study data and images from the NDAR Central Repository for research purposes. There are no capital, operating, and/or maintenance costs to the respondents.

There are two scenarios for completing the form. The first where the Principal Investigator (PI) completes the entire NDAR Data Access Request form, and the second where the PI has the Research Assistant begin filling out the form and PI provides the final reviews and signs it. The total estimated annual burden hours to complete data request form is listed below.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hours
NDAR Data Access Request	40	1	95/60	63