noracoordinator@cdc.gov, telephone (202) 245–0665.

Dated: November 1, 2012.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2012–27172 Filed 11–5–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations for Candidates To Serve on the National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for possible membership on the National Public Health Surveillance and Biosurveillance Advisory Committee (NPHSBAC). This committee provides advice and guidance to the Secretary of the Department of Health and Human Services and the Director of the Centers for Disease Control and Prevention, regarding the broad range of issues impacting the human health component of biosurveillance. The Committee will ensure that the Federal Government is meeting the goal of enabling State and local government public health surveillance capabilities. Specifically, this includes recommendations related to both traditional and innovative information sources of human health related data from State and local government public health authorities and appropriate private sector health care entities. This also includes recommendations to enable healthcare and public health information exchange.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Nominees will be selected based upon expertise in the field of public health surveillance and biosurveillance; multi-disciplinary expertise in public health; scientific and technical expertise. Whenever possible, nominees should be acknowledged experts in their fields whose credibility is beyond question. All nominees should have demonstrated skills in critical evaluation of data and communication skills necessary to promote efficient and effective deliberations.

Federal employees will not be considered for membership. Members may be invited to serve up to four-year terms. Consideration is given to representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: Name, affiliation, address, telephone number, and current curriculum vitae. Email addresses are requested if available.

Nominations should be sent, in writing, and postmarked by November 30, 2012 to: Vernellia Johnson, Management and Program Analyst, Public Health Surveillance and Informatics Program Office, Centers for Disease Control and Prevention, Office of Surveillance, Epidemiology and Laboratory Services, 2500 Century Center Boulevard, Room 3017, Atlanta, Georgia 30345 or via email to *hft9@cdc.gov.* Telephone and facsimile submissions cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 26, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–27053 Filed 11–5–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0748]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Drug User Fee Cover Sheet; Form FDA 3794

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 6, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Generic Drug User Fee Cover Sheet; Form FDA 3794.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Drug User Fee Cover Sheet; Form FDA 3794—(OMB Control Number 0910–New)

On July 9, 2012, the Generic Drug User Fee Act (GDUFA) (Pub. L. 112–144, Title 111) was signed into law by the President. GDUFA, designed to speed the delivery of safe and effective generic drugs to the public and reduce costs to industry, requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The user fees required by GDUFA are as follows: A one-time fee for original abbreviated new drug applications (ANDAs) pending on October 1, 2012, (also known as backlog applications); fees for type II active pharmaceutical ingredient (API) and final dosage form (FDF) facilities; fees for new ANDAs and prior approval supplements (PASs); and a one-time fee for drug master files (DMFs).

The purpose of this notice is to solicit feedback on the collection of information in an electronic form used to calculate and pay generic drug user fees. Proposed Form FDA 3794, the Generic Drug User Fee Cover Sheet, requests the minimum necessary information to determine if a person has satisfied all relevant user fee obligations. The proposed form is modeled on other FDA user fee cover sheets, including Form FDA 3397, the Prescription Drug User Fee Act Cover Sheet. The information collected would be used by the FDA to initiate the administrative screening of generic drug submissions and DMFs, support the inspection of generic drug facilities, and

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.