DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0879]

Notice of Opportunity To Withdraw Abbreviated New Drug Applications To Avoid Backlog Fee Obligations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to provide applicants who are no longer seeking approval of their pending original abbreviated new drug applications (ANDAs) with an opportunity to withdraw them as soon as possible to avoid paying a fee. The fee in question is a one-time backlog fee that was established through enactment of the Generic Drug User Fee Amendments of 2012 (GDUFA). It will apply to any original ANDA that is pending (neither withdrawn nor tentatively approved) at FDA on October 1, 2012. This notice is intended to allow applicants to decide which ANDAs they do not wish to pursue and by timely notice of withdrawal avoid paying the new backlog fee on such applications.

DATES: Under GDUFA, to avoid incurring the backlog fee, an ANDA applicant covered by this notice must submit written notification to FDA so that it is received by September 28, 2012. However, to expedite this process, applicants are encouraged to submit their written notification by September 15, 2012.

ADDRESSES: Applicants should submit written notification of the request for withdrawal by standard application submission methods. If an application was submitted by the FDA electronic gateway, a request for withdrawal should be submitted to the application by the gateway. In addition, a copy of the electronic notification of withdrawal should be emailed to *OGDGDUFA@fda.hhs.gov.* Alternatively, the applicant should send written notification to the ANDA archival file at the following address: Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Document Control Room, Metro Park North VII, 7620 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Thomas Hinchliffe, Center for Drug Evaluation and Research (HFD–617), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–9310, *OGDGDUFA@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Establishment of the Backlog Fee

On July 9, 2012, GDUFA (Pub. L. 112–144, Title III) was signed into law by the President. Designed to speed delivery of safe and effective generic drugs to the public and reduce costs to industry, GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable program enhancements. The new law includes a provision to assess user fees for any original ANDA that is pending on October 1, 2012, that has not been tentatively approved. Collection of fees for applications in the backlog will provide the Agency with necessary funding to reduce the backlog and prepare to meet the ANDA review performance goals established by GDUFA. Specifically, in the Commitment Letter that accompanies the law, FDA committed to review and act on 90 percent of all ANDAs pending on October 1, 2012, by the end of fiscal year 2017.

II. Backlog Fee Calculations for FY 2013

FDA will set the backlog fee rates for FY 2013 to generate a total of $50,000,000. Therefore, to determine the fee for a pending original ANDA, we will divide $50,000,000 by the number of original ANDAs that are pending on October 1, 2012, and have not been tentatively approved as of that date.

We have estimated that absent withdrawals there could be 3,000 pending original ANDAs on October 1, 2012. Some currently pending original ANDAs are old and incomplete, and FDA anticipates that applicants will withdraw many of them before October 1, 2012, to avoid incurring the backlog fee. If 2,000 original ANDAs were to remain, the backlog fee per ANDA would be $25,000. However, this is only an estimate; the final fee, which will be published along with payment instructions in a notice in the **Federal Register** by October 31, 2012, could be higher or lower.

III. Due Date and Penalty To Pay Backlog Fees

Payment of backlog fees will be due no later than 30 calendar days after publication in the **Federal Register** of a notice (to be issued by October 31, 2012) announcing the amount of the backlog fee. Applicants with original ANDAs that fail to pay the backlog fee by the due date will be placed on a publicly available arrears list, and FDA will not receive new ANDAs or supplements submitted by those applicants, or any affiliates [1] of those applicants, within the meaning of 505(j)(5)(A) of the Federal Food, Drug, and Cosmetic Act, until the outstanding fee is paid.

Note: The fee is an obligation to the U.S. Government, and failure to pay the fee may result in collection activities by the Government under applicable laws.

Dated: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Enabling Bioanalytical and Imaging Technologies.

Date: September 26, 2012.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301–435–0229, *kenneth.ryan@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Prevention Therapeutics.

Date: September 26, 2012.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

[1] GDUFA defines the term ''affiliate'' as a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls, or has the power to control, the other business entity; or a third party controls, or has power to control, both of the business entities.