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 It will apply to any original ANDA that is pending (neither withdrawn nor tentatively approved) at FDA on October 1, 2012.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.

[FR Doc. 2012–20947 Filed 8–22–12; 11:15 am]

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.

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

Contact Person: Careen K Tang-Toth, Ph.D, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 21, 2012.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–20927 Filed 8–24–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2012–0797]

National Maritime Security Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Maritime Security Advisory Committee (NMSAC) will meet on September 11–12, 2012 in the Washington, DC metropolitan area to discuss various issues relating to national maritime security. This meeting will be open to the public.

DATES: The Committee will meet on Tuesday, September 11, 2012 from 9 a.m. to 3:30 p.m., and Wednesday, September 12, 2012 from 9 a.m. to 12 p.m. This meeting may close early if all business is finished.

All written material and requests to make oral presentations should reach the Coast Guard on or before September 7, 2012.

ADDRESSES: The Committee will meet at the American Bureau of Shipping, 1400 Key Blvd., Suite 800, Arlington, Virginia 22209. Seating is very limited. Members of the public wishing to attend the open sessions should register with Mr. Ryan Owens, Alternate Designated Federal Official (ADFO) of NMSAC, telephone 202–372–1108 or *ryan.f.owens@uscg.mil* no later than September 7, 2012. Additionally, this meeting will be broadcasted via a Web enabled interactive online format and teleconference line.

To participate via teleconference, dial (866) 810–4853; the pass code to join is 9760138#. Additionally, if you would like to participate in this meeting via the online Web format, please log onto *http://connect.hsin.gov/nmsac91112/* and follow the online instructions to register for this meeting.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed below in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Committee as listed in the ''Agenda'' section below. Identify your comments by docket number [USCG–2012–0797], and submit them no later than September 7, 2012 by using one of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. We encourage use of electronic submissions because security screening may delay delivery of mail.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.
- *Instructions:* All submissions received must include the words ''Department of Homeland Security'' and docket number [USCG–2012–0797]. All submissions received will be posted without alteration at *www.regulations.gov*, including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the **Federal Register** (73 FR 3316).
- *Docket:* Any background information or presentations available prior to the meeting will be published in the docket. For access to the docket to read background documents or submissions received by the NMSAC, go to *www.regulations.gov*, and use ''USCG–2012–0797'' as your search term.

Public comment period will be held on September 11, 2012, from 3:00 p.m. to 3:30 p.m., and September 12, 2012 from 11:30 a.m. to 12 p.m. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period will end following the last call for comments. Contact the person listed below in the **FOR FURTHER INFORMATION CONTACT** section to register as a speaker.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Owens, ADFO of NMSAC, 2100 2nd Street SW., Stop 7581, Washington, DC 20593–7581; telephone 202–372–1108 or email *ryan.f.owens@uscg.mil.* If you have any questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 U.S.C. App. (Pub. L. 92–463). NMSAC operates under the authority of 46 U.S.C. 70112. NMSAC provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security.

Agenda of Meeting

The agenda for the Committee meeting is as follows:

Day 1

(1) *Maritime Domain Awareness and Information Sharing.* The Committee will hold a follow up discussion from its last meeting to discuss the results of the Committee's efforts to poll the maritime industry on what gaps still remain in information sharing between the industry and the Federal Government with a panel of Department of Homeland Security (DHS) Information Sharing Executives. The Committee will make recommendations on how to improve the information sharing efforts of the Coast Guard and DHS.

(2) *Cyber-Security.* The Committee will discuss the parameters of a new tasking from the Coast Guard to provide guidance/recommendations on cyber-security initiatives within the maritime sector.

(3) *Utilization of the Marine Highway for the Protection of Metropolitan Areas from Hazardous Cargo.* The Committee will receive a brief on effort by the Maritime Administration to reduce the risk of hazardous cargo in metropolitan areas by utilizing the Marine Highway system.

(4) *Detain On-Board Requirements.* NMSAC will receive an update on implementation of recommendations made by the NMSAC on April 19, 2012 on Coast Guard and U.S. Customs and Border Protection (CBP) field guidance pertaining to requirements for vessels to post or contract for guards while in US ports.

(5) *Transport Canada/Coast Guard Regulatory Harmonization.* The