generic FDFs. In the first year of the program, there would also be a fee assessed for applications that are pending on October 1, 2012, the so-called ''backlog''.

As under the prescription drug user fee act (PDUFA), individual fee amounts would be set annually, with the total annual revenue provided by the user fee specified in statute. Of the total generic drug user fee revenue, 80 percent would be provided by the FDF manufacturers and 20 percent by API manufacturers. Additionally, 70 percent of the overall GDUFA revenue would be generated by facility fees and 30 percent would be generated by submission fees; though in the first year those splits will be slightly different because of the one-time backlog fee.

While it is not possible to provide actual individual fee amounts until such fees are set by a **Federal Register** notice, it is expected that individual GDUFA fees will be orders of magnitude less than PDUFA fees, a factor due to the larger fee paying base in GDUFA. In negotiating the program, FDA was cognizant that generic drugs are a tremendous public health success story, responsible for saving $824 billion over the last decade. Consequently, the Agency worked to achieve a program that would not appreciably add to the cost of generic drugs, change the structure of the industry, or advantage any particular industry sector, regardless of size or location.

The program, as negotiated, is aimed at putting FDA's generic drugs program on a firm financial footing and providing additive resources necessary to assure timely access to safe, high-quality, affordable generic drugs.

III. What information should you know about the meeting?

A. When and where will the meeting occur? What format will FDA use?

Through this notice, we are announcing a public meeting to update stakeholders and hear stakeholder views on the negotiated proposal for a generic drug user fee program. We will conduct the meeting on December 19, 2011, from 10 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2047, Silver Spring, MD 20993. In general, the meeting format will include a presentation by FDA and presentations by stakeholders and members of the public who have registered in advance to present at the meeting. The amount of time available for presentations will be determined by the number of people who register to make a presentation. We will also provide an opportunity for organizations and individuals to submit written comments to the docket after the meeting. FDA policy issues are beyond the scope of this initiative. Accordingly, the presentations should focus on process and funding issues, and reactions to the GDUFA recommendations, and not focus on policy.

B. How do you register for the meeting or submit comments?

If you wish to attend and/or present at the meeting, please register by email to *GDUFA_Meeting4@fda.hhs.gov* by December 12, 2011. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization, as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early. If you need special accommodations because of disability, please contact Mari Long or Peter Beckerman (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, any person may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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. To ensure consideration, all comments must be received by January 6, 2012. Submission of comments prior to the meeting is strongly encouraged.

C. Will the meeting be Web cast?

For those unable to attend in person, FDA will Web cast and provide a telephone audio link to the meeting. To join the Web meeting, please go to *https://collaboration.fda.gov/gdufa/*. For audio, please call 301–796–2700 and enter participant code 121947. If you have never attended a Connect Pro meeting before, you may wish to test your connection by going to: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*.

D. Will meeting transcripts be available?

Please be advised that as soon as a transcript is available it will be accessible at *http://www.regulations.gov* and *http://www.fda.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM)-1029, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: December 5, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31630 Filed 12–6–11; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. app. 2), notice is hereby given of the following meeting:

Name: Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: January 26, 2012, 8:30 a.m. to 5 p.m. January 27, 2012, 8:30 a.m. to 3:30 p.m.

Place: Park Hyatt Hotel, 1201 24th Street NW., Washington, DC 20037.

Status: The meeting will be open to the public, but attendance will be limited by the space available. Participants are asked to register for the meeting by going to the registration Web site at *http://altarum.cvent.com/event/sachdncjan2012*. The registration deadline is Monday, January 23, 2012. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their needs on the registration Web site. The deadline for special accommodation requests is Tuesday, January 24, 2012. If there are technical problems gaining access to the Web site, please contact Maureen Ball, Meetings Coordinator, at *conferences@altarum.org.*

Purpose: The Secretary's Advisory Committee on Heritable Disorders in

Newborns and Children (Advisory Committee), as authorized by Public Law 106–310, which added section 1111 of the Public Health Service Act, codified at 42 U.S.C. 300b–10, was established by Congress to advise the Secretary in connection with the development of newborn screening activities, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. Recommendations for screenings that are adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP), which forms a part of the Comprehensive Guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans are required to cover screenings provided for in the Comprehensive Guidelines without charging a co-payment, co-insurance, or deductible for plan years (in the individual market these are known as policy years) beginning on or after the date that is one year from the Secretary's adoption of a screening(s). The Advisory Committee also provides advice and recommendations concerning grants and projects authorized under section 1109 of the Public Health Service Act (42 U.S.C. 300b–8).

Agenda: The meeting will include: (1) An orientation for all new Committee members including overviews of the Department of Health and Human Services, the Health Resources and Services Administration (HRSA), and the Maternal and Child Health Bureau; (2) the history of the Advisory Committee; (3) an overview of the authorizing legislation for the Advisory Committee; (4) updates from the Nomination and Prioritization workgroup, Public Health Impact Matrix workgroup and the Evidence Review workgroup; and (5) presentations on the continued work and reports of the Advisory Committee's subcommittees: Laboratory Standards and Procedures; Follow-up and Treatment; and Education and Training. Tentatively, the Advisory Committee is expected to review and/or vote on the following items: (1) Forwarding the 22q11 condition nomination package to the Evidence Review Workgroup for further evaluation; (2) reviewing the draft Public Health Impact Matrix; (3) forwarding the Hyperbilirubinemia condition nomination to the Public Health Impact Workgroup for further evaluation; (4) reviewing the report on Linking Birth Certificates and Serial Numbers; and (5) reviewing the report on Implementing Point of Care Newborn Screening.

Proposed agenda items are subject to change as priorities dictate. The Agenda, Committee Roster and Charter, presentations, and meeting materials can be found at the home page of the Advisory Committee's Web site at *http://www.hrsa.gov/heritabledisorderscommittee/.*

Public Comments: Members of the public can submit written comments and/or present oral comments during the public comment periods of the meeting. Time for public comments has been scheduled to occur during the afternoon of January 26, 2012. Those individuals who want to make oral comments are requested to register online by Monday, January 23, 2012 at *http://altarum.cvent.com/event/sachdncjan2012.* In order to be considered, written comments should be emailed no later than Tuesday, January 24, 2012. All comments, whether oral or written, should contain the name, address, telephone number, and any professional or business affiliation of the author. Groups having similar interests are requested to combine their comments and present them through a single representative. Submit written comments to Maureen Ball, Meetings Coordinator, Conference and Meetings Management, Altarum Institute, 1200 18th Street NW., Suite 700, Washington, DC 20036. Comments may also be faxed (202) 785–3083 or emailed (*conferences@altarum.org*). If you have additional questions regarding the submission of comments, please contact Ms. Ball at (202) 828–5100.

Contact Person: Anyone interested in obtaining other relevant information should contact or write to Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; *telephone:* (301) 443–1080; *email: dsarkar@hrsa.gov.* More information on the Advisory Committee is available at *http://mchb.hrsa.gov/heritabledisorderscommittee.*

Dated: December 2, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–31522 Filed 12–7–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* (301) 496–7057; *fax:* (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Novel NSAIDs for the Treatment of Human Diseases

Description of Technology: The invention relates to novel compounds which are hybrids between two moieties, *i.e.* non-steroidal anti-inflammatory drugs (NSAID) and Nitroxyl (HNO) releasing agents as well as Nitroxide (an antioxidant and superoxide scavenger). Such modified NSAIDs have shown to be advantageous to conventionally used NSAID, as their toxicity is significantly reduced and they can thus be used in medical treatment for extended periods of time without severe side effects. The adverse side effects (*i.e.* heart attack, thrombosis and severe gut toxicity) presented by conventional NSAIDs are well documented and some of them (*i.e.* Vioxx) were therefore withdrawn from the market. The present compounds may alleviate these problems, and may render more anti-inflammatory agents suitable for human use. The HNO releasing moiety of these novel compounds will expand the medical utility of these compounds, as HNO releasing agents possess anticancer activity as well as good antioxidant activities, a property that is beneficial for a variety of human diseases, including acute and chronic inflammation. In summary, the hybrid compounds provided in the invention can be useful in treatment of variety of human diseases (*i.e.* inflammatory diseases, heart diseases and cancer) with relatively low level of side effects.

Potential Commercial Applications: The drugs of this invention will be useful in treatment of anti-inflammatory diseases, and as therapeutic or preventative drugs for cardiovascular diseases, diabetes and cancer.

Competitive Advantages: The hybrid structure of the present drugs will render them useful in therapy and prevention of a wide variety of disorders, with reduced toxicity.

Development Stage: In vitro data available.

Inventors: David A. Wink *et al.* (NCI).

Publication: Flores-Santana W *et al.* Redox-Modified Non-Steroidal Anti-Inflammatory Drugs as Potential Anti-Cancer Agents with the SOD Mimetic Nitroxide. Br J Pharmacol. 2011 Jun 9; doi: 10.1111/j.1476–5381.2011.01527.x (Epub ahead of print). [PMID 21658022].

Intellectual Property: HHS Reference No. E–131–2011/0—U.S. Provisional