• Review and discussion of FDA's proposed 351(k) user fee program structure and any alternative structures submitted to the public docket in response to this document that would also meet the key design principles and criteria.

• Review and discussion of FDA's proposed performance goals for 351(k) applications. FDA will review and analyze the industry stakeholder input obtained through this process. FDA will take this information into account, as well as information obtained from public stakeholder consultation meetings, in developing the proposed set of recommendations that will be presented to Congressional Committee staff, published in the **Federal Register** for public review and comment, and presented at a public meeting to obtain public input. After the public meeting, the proposed recommendations would be revised as necessary before transmittal to Congress by January 15, 2012.

VI. Next Steps

A. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

FDA encourages members of the public to submit comments to the docket on the following topics:

Question VI.1: FDA-proposed principles for a fair and adequate 351(k) user fee program (section II of this document),

Question VI.2: FDA-proposed structure for a 351(k) user fee program that aligns with these principles (section III of this document), and

Question VI.3: FDA-proposed performance goals for a 351(k) user fee program for FYs 2013 through 2017 (section IV of this document).

FDA also encourages the public to submit comments to the docket concerning any potential alternative 351(k) user fee structures that would align with the proposed principles. When you submit comments to the docket, identify the section of this document and the number of each question you address. FDA plans to review the comments submitted to the docket, hold consultation meetings with public stakeholder groups, and hold industry stakeholder meetings, to refine the proposed recommendations for a 351(k) user fee program for FYs 2013 through 2017.

B. Public Stakeholder Identification

Public stakeholders who have not yet notified FDA that they wish to participate in these consultation meetings should notify FDA by e-mail to *BiosimilarsUserFeeProgram@fda.hhs.gov* on or before June 3, 2011. Your e-mail should contain complete contact information, including name, title, organization affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

C. Industry Stakeholder Identification

FDA is requesting that industry stakeholders, including industry associations with relevant interests and individual companies with ongoing efforts or interest in developing biosimilar and interchangeable biological products, identify their interest in participating in industry stakeholder meetings. The purpose of these industry stakeholder meetings is to hold a series of discussions to develop proposed recommendations for a user fee program for biosimilar and interchangeable biological product applications for FYs 2013 through 2017.

If you have not yet notified FDA that you are a company or trade association that would be affected by a 351(k) user fee program, please provide notification by e-mail to *BiosimilarsUserFeeProgram@fda.hhs.gov* on or before June 3, 2011. Your e-mail should contain complete contact information, including name, title, organization affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability.

VII. Additional Information on the BPCI Act

There are several sources of information on FDA's Web site that may serve as useful resources for stakeholders intending to participate in consultation meetings:

• The **Federal Register** document that announced the November 2010, public hearing and requested public comments is available at *http://edocket.access.gpo.gov/2010/pdf/2010-24853.pdf.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

• Comments submitted in response to the November 2010 public hearing document can be found at *http://www.regulations.gov* using Docket No. FDA–2010–N–0477.

• The **Federal Register** notice that requested notification of stakeholder intention to participate in consultation meetings is available at *http://edocket.access.gpo.gov/2010/pdf/2010-30713.pdf.*

• Additional information regarding implementation of the BPCI Act is available at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/UCM215031.*

Dated: May 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–11348 Filed 5–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Title (OMB No. 0915–NEW)—[NEW]

Authorized through the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (Pub. L. 109–18), as amended by the Patient Protection and Affordable Care Act (Pub. L. 111–148), the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP) supports the development and operation of projects to provide patient navigator services to improve health outcomes for individuals, including individuals with cancer and other chronic diseases, and health disparities populations. Award

recipients are to use grant funds to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate care for those who are at risk for or who have cancer or other chronic diseases and for outreach to health disparities populations.

As authorized by the statute, a report on the outcomes of the program must be submitted to Congress. The statute requires that the Report to Congress include a quantitative analysis of baseline and benchmark measures; aggregate information about the patients served and program activities; and recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas. The data collection instruments (see table) are intended to provide the data needed to produce the Report to Congress.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient Data Intake Form	4,827	1	4,827	0.5	2,413.5
VR–12 Health Status Form	4,827	2	9,654	.12	1,158.5
SubTotal-Patient Burden	4,827	.....	.....	.....	3,572
Patient Navigator Survey	46	1	46	0.2	9.2
Patient Navigator Encounter/Target Services Log	46	629.6	28,961.6	0.25	7,240.4
Patient Navigator Focus Group	46	1	46	1	46
SubTotal-Patient Navigator Burden	46	.....	.....	.....	7,295.6
Patient Medical Record and Clinic Data (no personally identifiable information)	10	482.7	4,827	.17	820.6
Annual Clinic-Wide Clinical Performance Measures Report	5	1	5	8	40
Patient Navigator Cultural Competency Checklist	10	4.6	46	1.17	53.8
Patient Navigator/Health System Administrator Focus Group	50	1	50	1	50
Grantee Health Care Provider Focus Group	30	1	30	1	30
Social Service Provider Focus Group	50	1	50	1	50
Quarterly Report	10	4	40	1	40
SubTotal-Grantee Burden	165	.....	.....	.....	1084.4
Totals	5,038	.....	48,582.6	.....	11,952
Total Average Annual Burden	.....	.....	.....	.....	11,952

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: May 5, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011–11396 Filed 5–9–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel, SBIR Contract Review.

Date: June 2, 2011.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: YingYing Li-Smerin, PhD, MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924. 301–435–0277. *lismerin@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Resource Related Research Project in National Biological Sample Data Repository.

Date: June 8, 2011.

Time: 1 p.m. to 3 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: Giuseppe Pintucci, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892. 301–435–0287. *Pintuccig@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–11398 Filed 5–9–11; 8:45 am]

BILLING CODE 4140–01–P