modify, or retain any element of the workload adjuster.

H. Impact of PDUFA V Enhancements on User Fee Revenue

Implementing the proposed enhancements discussed in the previous sections of this document will add $40.4 million to the PDUFA user fee revenue amount in FY 2012. The fee revenue amount for FY 2012 is $652,709,000 as published by notice in the **Federal Register** of August 1, 2011 (76 FR 45831). This amount includes the additional user fee revenues for drug safety in FY 2012 totaling $65 million as specified in the statute. The additional user fee revenue for the PDUFA V enhancements translates to a 6-percent increase, and a total base of $693.1 million in FY 2013. The following table summarizes the FY 2013 baseline and added resources to support the new PDUFA V enhancements:

Financial baseline	Dollars
FY 2012 Baseline [1]	$499,412,000
Cumulative Inflation Adjustment for FY 2012	104,277,000
Cumulative Workload Adjustment for FY 2012	49,020,000
Fee Revenue Amount for FY 2012 [2]	652,709,000
PDUFA V Enhancements	
Increased Staff Capacity (129 FTE)	36,120,000
Other Direct Costs	4,270,000
Total Statutory Revenue Amount for FY 2013 [3]	693,099,000

[1] In determining the fee revenue amount for FY 2012, sections 736(b)(4)(A) and 736(b)(4)(B) of the FD&C Act direct the Secretary of Health and Human Services (Secretary) to substitute $392,783,000 plus $65,000,000 (for FY 2012) for the amount in paragraph (1)(A). Furthermore, paragraph (1)(B) directs the Secretary to add the amount of the modified workload adjustment for FY 2007 to the amount in paragraph (1)(A) to determine the total revenue amount in FY 2012. This total is $499,412,000.

[2] As published in the **Federal Register** of August 1, 2011 (76 FR 45831).

[3] Of this amount, $652,709,000 will be further adjusted according to the new statutory provisions to account for inflation and workload adjustments in determining fees for FY 2013. These adjustments must be captured in calculations of user fee revenue for FYs 2014–2017.

IV. What information should you know about the meeting?

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

We will convene a public meeting to hear the public's views on the proposed recommendations for reauthorization of PDUFA. We will conduct the meeting on October 24, 2011, at FDA's White Oak Campus (see **ADDRESSES**). The meeting will include a presentation by FDA and a series of panels representing different stakeholder groups identified in the statute (such as patient advocacy groups, consumer advocacy groups, health professionals, and regulated industry). We will also provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket before the meeting.

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

If you wish to attend this meeting, please register by e-mail at: *PDUFAReauthorization@fda.hhs.gov* by October 10, 2011. Your e-mail should contain complete contact information for each attendee, including: Name, title, affiliation, address, e-mail address, and phone number. Registration is free and will be on a first-come, first-served basis, with the exception below. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. On-site 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. If you need special accommodations because of disability, please contact Sunanda Bahl (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

In addition, 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. To ensure consideration, all comments must be received by October 31, 2011.

C. 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 Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23251 Filed 9–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its Tobacco Products Scientific Advisory Committee, notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on the Tobacco Products Scientific Advisory Committee. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancies effective with this notice.

DATES: Send letters stating interest in participating in the selection process to FDA by October 12, 2011 (see sections I and II of this document for details). Concurrently, nomination material for prospective candidates should be sent to FDA by October 12, 2011.

ADDRESSES: All letters of interest and nominations should be submitted in writing to *TPSAC@fda.hhs.gov,* or by mail to Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), FAX: 240–276–3761, e-mail: *TPSAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency requests nominations for nonvoting industry representatives on the Tobacco Products Scientific Advisory Committee.

I. Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

The Committee includes three nonvoting members who represent industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative of the interests of the small business tobacco manufacturing industry may be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

With this notice, nominations are sought for the following positions: (1) One representative of the interests of tobacco growers, and an alternate to this representative; (2) a pool of individuals, with varying areas of expertise, to represent the interests of the small business tobacco manufacturing industry on a rotating, sequential basis; and (3) an individual to serve as alternate to the representative of the tobacco manufacturing industry.

II. Selection Procedure

Any industry organization interested in participating in the selection of appropriate nonvoting member(s) to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT** and **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the letter, to serve as the nonvoting member to represent industry interests on the Committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent the industry interests.

III. Application Procedure

Individuals may self-nominate and/or organizations may nominate one or more individuals to serve as a nonvoting industry representative (for the roles specified in this document). Nominations must include a current resume or curriculum vitae of the nominee including current business address and/or home address, telephone number, e-mail address if available, and the role for which the individual is being nominated. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA has a special interest in ensuring that women, minority groups, and individuals with physical disabilities are adequately represented on its advisory committees and, therefore, encourages nominations for appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23185 Filed 9–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 meeting.

The meeting 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, ''NIAID Contract Review Meeting 2011''.

Date: October 3, 2011.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Brandt R. Burgess, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethdesda, MD 20892–7616, (301) 451–2584, *bburgess@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 6, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–23231 Filed 9–9–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; The NIDDK–KUH Fellowship Review.

Date: October 6, 2011.

Time: 9 a.m. to 12 p.m.