TABLE 6—FEE-PAYING FULL APPLICATION EQUIVALENT—5-YEAR AVERAGE

Fiscal Year	2004	2005	2006	2007	2008	5-Year Average
Fee-Paying FAEs	145.1	121.5	136.7	134.4	144.7	136.5

The FY 2009 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 136.5, into the fee revenue amount to be derived from application fees in FY 2009, $170,222,000. The result, rounded to the nearest $100, is a fee of $1,247,200 per full application requiring clinical data, and $623,600 per application not requiring clinical data or per supplement requiring clinical data.

IV. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2008, the establishment fee was based on an estimate that 390 establishments would be subject to, and would pay, fees. By the end of FY 2008, FDA estimates that 435 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. As in previous years, FDA again estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2008. In addition, FDA estimates that another 10 full establishment fees will be exempted this year based on the orphan drug exemption in the Food and Drug Administration Amendments Act of 2007 (FDAAA) (see section 736(k) of the act). Subtracting 35 establishments (25 plus the estimated 10 establishments under the orphan exemption) from 435 leaves a net of 400 fee-paying establishments. FDA will use 400 for its FY 2009 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($170,222,000) by the estimated 400 establishments, for an establishment fee rate for FY 2009 of $425,600 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2008, the product fee was based on an estimate that 2,355 products would be subject to, and would pay, product fees. By the end of FY 2008, FDA estimates that 2,450 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. FDA assumes that there will be about 40 waivers and reductions granted, the same amount estimated last year. In addition, FDA estimates that another 30 product fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the act). FDA estimates that 2,380 products will qualify for product fees in FY 2008, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2009 estimate. Accordingly, the FY 2009 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($170,222,000) by the estimated 2,380 products for a FY 2009 product fee of $71,520 (rounded to the nearest $10).

V. Fee Schedule for FY 2009

The fee rates for FY 2009 are set out in Table 7 of this document.

TABLE 7

Fee Category	Fee Rates for FY 2009
APPLICATIONS	
Requiring clinical data	$1,247,200
Not requiring clinical data	$623,600
Supplements requiring clinical data	$623,600
ESTABLISHMENTS	$425,600
PRODUCTS	$71,520

VI. Implementation of Adjusted Fee Schedule

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received after September 30, 2008. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee ID number on your check. Your payment can be mailed to: Food and Drug Administration, P.O. Box 70963, Charlotte, NC 28272–0963.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. NC0810, Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 70963) is written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payment may also be used. The routing and transit number is 021030004 and the account number is 75060099.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2009 under the new fee schedule in August 2008. Payment will be due on October 1, 2008. FDA will issue invoices in November 2009 for any products and establishments subject to fees for FY 2009 that qualify for fees after the August 2008 billing.

Dated: July 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17738 Filed 7–31–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 17–18, 2008.

Closed: September 17, 2008, 5:30 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Open: September 18, 2008, 9 a.m. to 3:30 p.m.

Agenda: Program reports and presentations.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Abraham P. Bautista, PhD, Executive Secretary, National Institute on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 3039, Rockville, MD 20852, 301–443–9737, *bautistaa@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://silk.nih.gov/silk/niaaa1/about/roster.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: July 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–17583 Filed 7–31–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 grant applications and/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering; NACBIB September 2008.

Date: September 16, 2008.

Open: 9 a.m. to 12:30 p.m.

Agenda: Report from the Institute Director, other Institute staff and presentations of working group reports.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Closed: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Anthony Demsey, PhD, Director, National Institute of Biomedical Imaging and Bioengineering, 6701 Democracy Blvd., Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm*, where an agenda and any additional information for the meeting will be posted when available.

Dated: July 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–17586 Filed 7–31–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Eye Institute Special Emphasis Panel; K08, K23, K99–NEI Research Training Applications.

Date: August 8, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division Of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300 Msc 9300, Bethesda, MD 20892–9300, 301–451–2020, *rawlings@nei.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Conference Grant Review.

Date: August 26, 2008.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division Of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300 Msc 9300, Bethesda, MD 20892–9300, 301–451–2020, *rawlings@nei.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–17584 Filed 7–31–08; 8:45 am]

BILLING CODE 4140–01–M