train and support health care providers and other professionals in public and private agencies who serve Florida's CYSHCN, helping them better understand the needs of children, youth and their families.

The Family Café will receive funding through May 31, 2011 to continue the same state-wide services as previously outlined in the originally competed and approved grant application submitted by FIFI. This replacement award will maintain Congress' mandate under the 2005 Budget Deficit Reduction Act/ Family Opportunity Act and the Patient Protection and Affordable Care Act (Pub. L. 111–148) that there shall be an F2F HIC in all 50 states and the District of Columbia by June 2009. It will also ensure that an F2F HIC will be accessible to families and professionals to continue providing essential information, referral and support services to families with CYSHCN throughout Florida and in a manner which avoids any disruption of services.

Dated: September 3, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–22663 Filed 9–10–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0463]

Fee for Using a Priority Review Voucher in Fiscal Year 2011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates for using a tropical disease priority review voucher for fiscal year (FY) 2011. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by title XI of the Food and Drug Administration Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for approval of drug or biological products when those applications use a priority review voucher awarded by the Secretary of Health and Human Services. These vouchers are awarded to the sponsor of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee to be submitted to FDA with applications using a priority review voucher is determined each fiscal year (FY) based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY.

This notice establishes the priority review fee rate for FY 2011.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1102 of FDAAA added new section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of certain tropical diseases by offering additional incentives for obtaining FDA approval of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a qualified tropical disease (as defined in section 524(a)(3)), shall receive a priority review voucher upon approval of the tropical disease product application. The recipient of a priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (21 U.S.C. 262), or transfer (including by sale) the voucher to another party that may then use it. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months.

The applicant that uses a priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA has published a draft guidance on its Web site about how this priority review voucher program will operate (available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf*).

This notice establishes the priority review fee rate for 2011 of $4,582,000, and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2010, and will remain in effect through September 30, 2011, for applications submitted with a priority review voucher, and the payment of this priority review user fee is required in addition to the payment of any other fee that would normally apply to such an application under PDUFA before FDA considers the application complete and acceptable for filing.

II. Priority Review User Fee for FY 2011

Under section 524(c)(2) of the FD&C Act, the amount of the priority review user fee is to be determined each FY based on the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous FY.

A priority review is a review conducted with a PDUFA goal date of 6 months. Normally, an application for a Center for Drug Evaluation and Research (CDER) product will qualify for a priority review if FDA determines that the product, if approved, would provide safe and effective therapy where no satisfactory alternative therapy exists or would be a significant improvement compared to marketed products, including non-drug products and/or therapies, in the treatment, diagnosis, or prevention of a disease. A Center for Biologics Evaluation and Research (CBER) product will qualify for a priority review if FDA determines that the product, if approved, would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. FDA has committed to a goal to review and act on 90 percent of the applications that have been granted priority review status no later than 6 months after receipt. An application that does not receive a priority designation will receive a "standard" review. Under the goals identified in the letters referenced in section 101(c) of FDAAA, FDA commits to a goal to review and act on 90 percent of "standard" applications within 10 months of the date of receipt. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. Because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked and kept. FDA started by using data that the Agency estimates and publishes on its Web site each year—standard costs for review. FDA does not publish a standard cost for "the review of a human drug application subject to priority review in the previous fiscal year." However, we expect all such applications would contain clinical data. The standard cost application

categories with clinical data that FDA does publish each year are as follows:

(1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and

(2) Biologic license applications (BLAs).

The worksheets for standard costs for FY 2009, the latest year for which standard cost data are available, show a standard cost of $4,021,000 (rounded to the nearest thousand dollars) for an NDA with clinical data and $3,530,000 (rounded to the nearest thousand dollars) for a BLA. Based on these standard costs, the total cost to review the 55 applications in these 2 categories in FY 2009 (24 BLAs and 31 NDAs with clinical data) was $209,371,000. (Note: no investigational new drug (IND) review costs are included in this amount; they will be calculated separately and added in the next paragraph.) Records acquired from CDER and CBER by the Office of Policy, Planning and Budget (OPPB), Economics Staff, indicate that a total of 17 of these applications (8 NDAs [excluding the President's Emergency Plan for Aids Relief NDAs] and 9 BLAs) received priority review, which would mean that the remaining 38 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, OPPB estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject. In the article "Developing Drugs for Developing Countries," published in *Health Affairs*, vol. 25, Number 2, in 2006, the analysis by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the midpoint of this range. Using FY 2009 figures, the costs of a priority and standard review are estimated using the following formula:

(17*a* x 1.67) + (38*a*) = $209,371,000

where "*a*" is the cost of a standard review and "*a*" times 1.67 is the cost of a priority review. Using this formula, the cost of a standard review for NMEs is calculated to be $3,154,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NMEs is 1.67 times that amount, or $5,267,000 (rounded to the nearest thousand dollars).

Next, the cost of the IND review phase for these applications is calculated. The standard lifetime cost of reviewing a drug IND in FY 2009 was $291,000 (rounded to the nearest thousand dollars). The standard lifetime cost of a biologic IND review in FY 2009 was $860,000 (rounded to the nearest thousand dollars). Because there were 8 priority NDAs and 9 priority BLAs received in FY 2009, the following formula estimates the average cost of the IND review phase of an application:

(8 NDAs x $291,000) + (9 BLAs x $860,000) = $10,068,000

This is the full cost of the IND review associated with the 17 priority review applications received in FY 2009. Dividing $10,068,000 by 17 (the total number of priority review applications received in FY 2009), yields an average IND review phase cost of $592,000 (rounded to the nearest thousand dollars) per priority review application.

Adding the cost of the NDA/BLA priority review calculated previously, $5,267,000, to the cost of the IND review phase of $592,000, results in an estimated average cost for priority review for an application received in FY 2009 of $5,859,000.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. FDA is setting fees for FY 2011, and the previous FY is FY 2010. However, the FY 2010 submission cohort has not been closed out yet, and the cost data for FY 2010 are not complete. The latest year for which FDA has data is FY 2009. Accordingly, FDA will adjust the previously mentioned FY 2009 cost figure by the average amount by which FDA's average salary and benefit costs increased in the 5 years prior to FY 2011, to adjust the FY 2009 amount for cost increases in FY 2010. That figure, published in the **Federal Register** of August 4, 2010 (75 FR 46952 at 46954), which set Prescription Drug User Fees for FY 2011, is 4.53 percent. Increasing the FY 2009 average priority review cost figure of $5,859,000 by 4.53 percent results in an estimated cost of $6,124,000 (rounded to the nearest thousand dollars).

FDA will deduct from this amount the PDUFA fee that must also be paid in addition to the priority review fee when an NDA or BLA with clinical data is submitted in FY 2011. That amount, also published in the **Federal Register** of August 4, 2010 (75 FR 46952 at 46957), which set PDUFA fees for FY 2011, is $1,542,000. The difference, rounded to the nearest thousand dollars, is $4,582,000. This is the priority review user fee amount for FY 2011 that must be submitted with a priority review voucher in FY 2011, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2011

The fee rate for FY 2011 is set out in table 1 of this document.

TABLE 1.

FEE CATEGORY	FEE RATE FOR FY 2011
APPLICATIONS SUBMITTED WITH A PRIORITY REVIEW VOUCHER	
In addition to the normal PDUFA Fee	$4,582,000

IV. Implementation of Priority Review Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of the application for which the priority review voucher is used. Section 524(c)(4)(B) specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act, and FDA may not collect priority review voucher fees prior to a relevant appropriation for fees for that FY. Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that "priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended." (Public Law 111–8, Section 5, Division A, Title VI).

The priority review fee established in the new fee schedule must be paid for any application that is received after September 30, 2010, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. 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. The user fee identification (ID) number should be included on the check, followed by the words "Priority Review". Payments can be mailed to: Food and Drug Administration, P.O. Box 70963, Charlotte, NC 28272–0963.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: Wells Fargo QLP Lockbox D1113–022, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., Charlotte,

NC 28262. (Note: This Wells Fargo address is for courier delivery only.) The FDA post office box number (P.O. Box 70963) must be written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payments may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD 20850.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of Treasury to utilize Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after the user fee ID number is generated.

Dated: September 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–22760 Filed 9–10–10; 8:45 am]

BILLING CODE 4160–01–S

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: Prions, HCV and Beta-Lactams.

Date: September 23–24, 2010.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rolf Menzel, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, MSC 7808, Bethesda, MD 20892, 301–435–0952, *menzelro@csr.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: Center for Scientific Review Special Emphasis Panel; Dental and Oral Sciences.

Date: October 4, 2010.

Time: 2 p.m. to 5 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: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: October 6, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Yi-Hsin Liu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, *liuyh@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, and Regeneration Study Section.

Date: October 6–7, 2010.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Savoy Suites Hotel, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Joanne T. Fujii, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, 301–435–1178, *fujiij@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: October 7, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Joanne T. Fujii, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4184, MSC 7850, Bethesda, MD 20892, 301–435–1178, *fujiij@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Fellowship: Biomedical Imaging and Bioengineering.

Time: 11:30 a.m. to 4 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: Dharam S Dhindsa, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892,(301) 435–1174, *dhindsad@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR09–057: Improving Interventions for Communication Disorders.

Date: October 18, 2010.

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

Agenda: To review and evaluate grant applications, JW Marriott San Francisco Union Square, 500 Post Street corner of Post and Mason, San Francisco, CA 94102.

Contact Person: Eugene Carstea, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov.*

Name of Commitee: Center for Scientific Review Special Emphasis Panel PAR09–056: Improving Intervention Possibilities for Communication Disorders.

Date: October 18, 2010.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott San Francisco Union Square, 500 Post Street corner of Post and Mason, San Francisco, CA 94102.

Contact Person: Eugene Carstea, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Old mice.

Date: October 18, 2010.

Time: 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 3222, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: James Harwood, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7840, Bethesda, MD 20892, 301–435–1256, *harwoodj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR–08–076: Community Participation Research.

Date: October 19, 2010.

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

Agenda: To review and evaluate grant applications.