

CFDA Number: 93.504.

Justification for the Exception to Competition: The former grantee, P2P of Vermont, has relinquished all grants held under the P2P legal name due to an organizational merger with VFN. The former grantee has requested that HRSA transfer the F2F HIC funds to VFN in order to implement and carry out grant activities originally proposed under P2P of Vermont grant applications.

A single-source award was made to VFN because of the organizational merger of P2P into VFN and the following program determinations: (1) Continuing need for the project; (2) that the time required to obtain competition would seriously jeopardize the success of the project and put at risk the health of the people being served by the project; (3) that there will be no significant change in the scope or objectives (including any reduction) of the previously approved project or activity; (4) that the replacement recipient is eligible to receive the award and its facilities and resources allow for the successful performance of the project.

CYSHCN are defined as “those children and youth who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally” (American Academy of Pediatrics, 1998). This is particularly relevant since 2006 National survey data showed more than 17% of CYSHCN in Vermont had problems getting referrals to care. Also, because of changes occurring in State services and funding for CYSHCN, many families and providers alike need to be kept up to date on these changes so that they can access appropriate services. This center is urgently needed to address these gaps and disparities in information and services.

It is critical that VFN continue helping families of CYSHCN gain access to information they need to make informed health care decisions, be full partners in decisionmaking, and access needed resources/referrals and financing for those services in the state of Vermont. It is also imperative that the center continues to train and support health care providers and other professionals in public and private agencies who serve Vermont’s CYSHCN, helping them better understand the needs of children, youth and their families.

VFN 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 the P2P of Vermont. 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 Vermont and in a manner which avoids any disruption of services.

Dated: September 3, 2010.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Family-to-Family Health Information Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring the Florida Family-to-Family Health Information Center (F2F HIC) grant (H84MC00006) from the Florida Institute of Family Involvement (FIFI) to the Family Café in Tallahassee due to financial difficulties resulting in closure of FIFI facilities and programs. This action ensures the continued provision of health resources, financing, related services and parent-to-parent support for families with children and youth with special health care needs (CYSHCN) in the state of Florida.

FOR FURTHER INFORMATION CONTACT: LaQuanta Person, Project Officer, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18A–18, Rockville, MD 20857; 301.443.2370; lperson@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Florida Institute of Family Involvement.

Original Grant Period: June 1, 2006 to May 31, 2011.

Replacement Awardee: The Family Café.

Amount of Replacement Award: Up to \$95,700 for the remaining of the project period.

Period of Replacement Award: The period of support for the replacement award is June 1, 2010 to May 31, 2011.

Authority: Section 501(c)(1)(A) of the Social Security Act, as amended.

CFDA Number: 93.504.

Justification for the Exception to Competition: The former grantee, FIFI, has relinquished all grants due to financial difficulties resulting in closure of FIFI facilities and programs. The former grantee has requested that HRSA transfer the F2F HIC funds to the Family Café in order to implement and carry out grant activities originally proposed under FIFI grant applications.

A single-source award was made to the Family Café because of the financial difficulties of FIFI and the following program determinations: (1) Continuing need for the project; (2) that the time required to obtain competition would seriously jeopardize the success of the project and put at risk the health of the people being served by the project; (3) that there will be no significant change in the scope or objectives (including any reduction) of the previously approved project or activity; (4) that the replacement recipient is eligible to receive the award and its facilities and resources allow for the successful performance of the project.

CYSHCN are defined as “those children and youth who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally” (American Academy of Pediatrics, 1998). This is particularly relevant since 2006 National survey data showed more than 26% of CYSHCN in Florida had problems getting referrals to care. Florida was ranked fourth nationally for the highest estimated number of CYSHCN in the state (551,263). In addition, because of changes occurring in state services and funding for CYSHCN, many families and providers alike need to be kept up to date on these changes so that they can access appropriate services. This center is urgently needed to address these gaps and disparities in information and services. It is critical that the Family Café continue helping families of CYSHCN gain access to information they need to make informed health care decisions, be full partners in decision-making and access needed resources/referrals and financing for those services in the state of Florida. It is also imperative that the center continues to

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.

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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