

### III. Priority Review Fee Schedule for FY 2012

The fee rate for FY 2012 is set out in table 1 of this document:

TABLE 1—PRIORITY REVIEW  
SCHEDULE FOR FY 2012

Fee category	Fee rate for FY 2012
Applications Submitted With a Priority Review Voucher in Addition to the Normal PDUFA Fee .....	\$5,280,000

### 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." (Pub. L. 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, 2011, 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 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only.) The FDA post

office box number (P.O. Box 979107) 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.

Dated: August 24, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–22062 Filed 8–29–11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0607]

#### FDA's Public Database of Products With Orphan-Drug Designation: Replacing Non-Informative Code Names With Descriptive Identifiers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Orphan Products Development, is announcing that it has replaced non-informative code names with descriptive identifiers on its public database of products that have received orphan-drug designation. The Orphan Drug Act mandates that FDA provide notice to the public respecting the designation of a drug as an orphan-drug. FDA typically provides public notice by publishing a drug's generic or trade name upon orphan designation. Where a designated drug does not have a generic or trade name, publishing a non-informative code name does not meet the statutory disclosure requirement because the public would not be able to identify the drug that has received orphan designation.

#### FOR FURTHER INFORMATION CONTACT:

Jeffrey Fritsch, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5276, Silver Spring,

MD 20993, 301–796–8660, e-mail: [OPDAR@FDA.HHS.GOV](mailto:OPDAR@FDA.HHS.GOV).

**SUPPLEMENTARY INFORMATION:** FDA publishes the generic name and/or trade name of a drug on its Web site at <http://www.fda.gov/orphan> after it designates a drug as an orphan drug. It has come to our attention that a small subset of drugs that have received orphan designation were published on our public database with non-informative code names. After careful consideration of this matter, we have concluded that the Orphan Drug Act mandates that FDA identify to the public products that have received orphan-drug designation. If a drug has no generic or trade name, publishing a non-informative code name for that drug does not meet the statutory notice requirement because the public would not be able to identify the drug that has received orphan designation.

In addition to issuing this notice, FDA has mailed letters to affected sponsors at their last known address and has posted notification on its Web site at <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/ucm267378.htm>. We informed sponsors that, on our Web site, we have replaced all non-informative code names with descriptive identifiers. We asked that these sponsors notify us within 20 days of the date of the letter if they believe that their product's current identifier did not accurately identify their product to the public.

Despite reasonable efforts, we were unable to notify a small proportion of affected sponsors. It appears that some sponsors may have gone out of business or may have transferred ownership of, or beneficial interest in, orphan-drug designation without informing FDA. (We remind sponsors of their obligations to notify us of any change in ownership of orphan-drug designation, under 21 CFR 316.27, and to submit brief progress reports to us on an annual basis, under 21 CFR 316.30.)

Through this document, FDA seeks to inform sponsors whom the Agency has not otherwise been able to notify that, under the Orphan Drug Act's notice requirements, all non-informative codes in our public orphan drug designations database have been replaced with corresponding informative identifiers.

If you believe this notice applies to you, please visit our Web site at <http://www.fda.gov/orphan>. Under "Resources for You," click on the "Search for Orphan Drug Designations and Approvals" and enter your product. If you believe that your product's current identifier does not accurately identify your product to the public,

please promptly contact Jeffrey Fritsch (see **FOR FURTHER INFORMATION CONTACT**).

Dated: August 25, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–22144 Filed 8–29–11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Refugee Resettlement

#### Award of an Urgent Single-Source Grant to Survivors of Torture International (SOTI) in San Diego, CA; Correction

**AGENCY:** Office of Refugee Resettlement, ACF, HHS.

**ACTION:** Notice; correction.

*CFDA Number:* 93.604.

**SUMMARY:** The Office of Refugee Resettlement, ACF, HHS published a document in the **Federal Register** of August 16, 2011 (76 FR 50744), concerning the issuance of an urgent single-source grant to Survivors of Torture, International (SOTI), San Diego, CA. The document contained incorrect information in citing the statutory authority for making this award.

**Correction:** In the **Federal Register** of August 16, 2011 (76 FR 50744), ORR omitted the primary authority for issuing this award. The notice should have included the following: Awards announced in this notice are authorized by the Torture Victims Relief Act (TVRA) of 1998,” Public Law 105–320 (22 U.S.C. 2152 note), reauthorized by Public Law 109–165 in January 2006. Section 5 (a) of the TVRA of 1998 provides for “Assistance for Treatment of Torture Victims. — The Secretary of Health and Human Services may provide grants to programs in the United States to cover the cost of the following services: (1) Services for the rehabilitation of victims of torture, including treatment of the physical and psychological effects of torture. (2) Social and legal services for victims of torture. (3) Research and training for health care providers outside of treatment centers, or programs for the purpose of enabling such providers to provide the services described in paragraph (1).” And by Section 412 (c)(1)(A) of the Immigration and Nationality Act (INA) (8 U.S.C. 1522(c)(1)(A), as amended, and the Refugee Assistance Extension Act of 1986, Public Law 99–605, Nov 6, 1986, 100 Stat. 3449.

#### FOR FURTHER INFORMATION CONTACT:

Ronald Munia, Director, Division of Community Resettlement, Office of Refugee Resettlement, 901 D Street, SW., Washington, DC 20047. Telephone: 202–401–4559. E-mail: [Ronald.Munia@acf.hhs.gov](mailto:Ronald.Munia@acf.hhs.gov).

Dated: August 24, 2011.

**Eskinder Negash,**

*Director, Office of Refugee Resettlement.*

[FR Doc. 2011–22196 Filed 8–29–11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

#### Project: Services Accountability Improvement System—(OMB No. 0930–0208)—Revision

This revised instrument will allow SAMHSA to collect information on two new strategic initiatives—*Trauma and Violence* and *Military Families*. The new items will be added to the Services Accountability Improvement System (SAIS), which is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through SAIS for approximately 600 grantees. Substance abuse treatment facilities submit their data on a monthly and even a weekly basis to ensure that SAIS is an accurate, up-to-date reflection on the scope of services delivered and characteristics of the treatment population. Over 30 reports on grantee performance are readily available on the SAIS website. The reports inform staff on the grantees’ ability to serve their target populations and meet their client and budget targets. SAIS data allow grantees information that can guide modifications to their service array.

With the addition of new questions regarding military families, experiences with trauma, and experiences with violence GFA, there is a proposed new

data collection instrument up for comment.

Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

CSAT has increased the number of questions in the instrument to satisfy reporting needs. The following paragraphs present a description of the changes made to the information collection. These questions will be contained in new sections in the GPRA tool. *Section H. Violence and Trauma*—CSAT proposes to add the following 6 items in a new section entitled “Violence and Trauma”.

1. Have you ever experienced violence or trauma in any setting (including community or school violence; domestic violence; physical, psychological, or sexual maltreatment/assault within or outside of the family; natural disaster; terrorism; neglect; or traumatic grief)? No, (skip to next section)

2. Did any of these experiences feel so frightening, horrible, or upsetting that in the past and/or the present that you:

2a. Have had nightmares about it or thought about it when you did not want to?

2b. Tried hard not to think about it or went out of your way to avoid situations that remind you of it?

2c. Were constantly on guard, watchful, or easily startled?

2d. Felt numb and detached from others, activities, or your surroundings?

3. In the past 30 days, how often have you been hit, kicked, slapped, or otherwise physically hurt?

• *Experiences with Violence and Trauma*—One of SAMHSA’s 10 Strategic Initiatives is trauma and violence. In order to capture this information, CSAT is adding six new questions to be asked of respondents. This information will help in SAMHSA’s overall goal of reducing the behavioral health impacts of violence and trauma by encouraging substance abuse treatment programs to focus on trauma-informed services.

*Section L. Military Family and Deployment*—CSAT proposes to add the following 6 new items in a new section entitled “Military Family and Deployment”.

1. Have you ever served in the Armed Forces, in the Reserves, or the National Guard [select all that apply]? No, (Skip to #2)

1b. Are you currently on active duty in the Armed Forces, in the Reserves, or the National Guard [select all that apply]?

1c. Have you ever been deployed to a combat zone?

2. Is anyone in your family or someone close to you on active duty in the Armed