

## ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
New Sponsor Form .....	55,200	1	.25/hour .....	13,800
Transfer Request and Tracking Form .....	1,000	1	.25/hour .....	250
Long Term Foster Care Placement Memo .....	279	1	.1/hour .....	28
Travel Request Form for UC Long Term Foster Care .....	20	1	.25/hour .....	5
Notice of Transfer to ICE Chief Counsel and Change of Address .....	2,320	1	.1/hour .....	232
Care Provider Family Reunification Checklist .....	55,200	1	.1 .....	5,520
Release Request .....	55,200	3	.25 hour .....	41,400
Discharge Notification .....	716	1	.25/hour .....	179
Verification of Release .....	55,200	1	.1/hour .....	5,520
Child Advocate Referral and Appointment Form .....	250	1	.50 .....	125
Notice of Rights and Provision of Services Handout .....	58,000	1	.1/hour .....	5,800
Legal Service Provider List for UC .....	58,000	1	.1 .....	5,800
URM Application .....	350	1	1 .....	350
Withdrawal of Application or Declination of Placement Form .....	10	1	.1/hour .....	1
Standard Shelter Tour Request .....	60	1	.1/hour .....	6

*Estimated Total Annual Burden Hours:* 172,636.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Email: OIRA\_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.676]

#### Announcement of the Award Two Single-Source Program Expansion Supplement Grant to Southwest Keys, Inc., Austin, TX.

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

**ACTION:** Notice of Award of two (2) single-source program expansion supplement grant to Southwest Keys, Inc. (SWK), in Austin, TX.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), announces the award of two (2) single-source program expansion supplement grant for \$26,254,260 and \$16,647,310 under the Unaccompanied Children's (UC) Program to support a program expansion supplement.

ORR has been identifying additional capacity to provide shelter for potential increases in apprehensions of Unaccompanied Children at the U.S. Southern Border. Planning for increased shelter capacity is a prudent step to ensure that ORR is able to meet its responsibility, by law, to provide shelter for Unaccompanied Children referred to its care by the Department of Homeland Security (DHS).

SWK has the infrastructure, licensing, and experience to meet the service requirements and the urgent need for expansion of capacity.

**DATES:** Supplemental award funds will support activities from October 1, 2015 through September 30, 2016.

#### FOR FURTHER INFORMATION CONTACT:

Jalyn Sualog, Director, Division of Children's Services, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: [DCSProgram@acf.hhs.gov](mailto:DCSProgram@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** ORR is continuously monitoring its capacity to shelter the unaccompanied children referred to HHS, as well as the information received from interagency partners, to inform any future decisions or actions.

ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing program and its services through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Children referred to its care by DHS and so that the US Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

**Statutory Authority:** This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85-4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110-457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85-4544-RJK (C.D.

Cal. 1996), pertinent regulations and ORR policies and procedures.

**Christopher Beach,**

*Senior Grants Policy Specialist, Office of Administration, Office of Financial Services, Division of Grants Policy.*

[FR Doc. 2016-14378 Filed 6-16-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2013-E-0681 and FDA-2013-E-0676]

**Determination of Regulatory Review Period for Purposes of Patent Extension; ZILVER PTX DRUG ELUTING PERIPHERAL STENT**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ZILVER PTX DRUG ELUTING PERIPHERAL STENT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications by Boston Scientific Scimed, Inc., to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 16, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 14, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your

comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket Nos. FDA-2013-E-0681 and FDA-2013-E-0676 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ZILVER PTX DRUG ELUTING PERIPHERAL STENT." Received comments will be placed in the dockets and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on [http://](http://www.regulations.gov)

[www.regulations.gov](http://www.regulations.gov). Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension