contact Allyssa Allen at 410–786–8436126.)

Dated: June 6, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award of 48 Single-Source Low-Cost Extension Supplement Grants Within the Office of Refugee Resettlement's Unaccompanied Alien Children's (UAC) Program

AGENCY: Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Notice of Award of 48 single-source low-cost extension supplement grants under the Unaccompanied Alien Children's (UAC) Program.

SUMMARY: ACF, ORR, announces the award of 48 single source low-cost extension supplement grants for a total of $110,480,457 under the Unaccompanied Alien Children's (UAC) Program.

DATES: Low-cost extension supplement grants will support activities from October 1, 2016, through December 31, 2016, for 46 grantees and October 1, 2016, through March 31, 2017, for two grantees.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Director, Division of Unaccompanied Children's Operations, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201. Email: *DCSProgram@acf.hhs.gov.* Phone: 202–401–4997.

SUPPLEMENTARY INFORMATION: The following supplement grants will support the immediate need for additional capacity of shelter services to accommodate the prior increase in number of UACs referred by DHS into ORR care. This increase in the UAC population necessitated the need for expansion of services to expedite the release of UAC. In order to be prepared for an increase in referrals for shelter services, ORR solicited proposals from grantees to accommodate the extensive amount of referrals from DHS.

Location	Grantee	Amount
U.S. Multi-City	BCFS Health and Human Services	$3,413,200
U.S. Multi-City	Southwest Key, Inc	1,036,081
U.S. Multi-City	United States Conference of Catholic Bishops	706,881
U.S. Multi-City	Crittenton	298,324
	Children's Village	286,202
U.S. Multi-City	MercyFirst	122,186
U.S. Multi-City	United States Committee for Refugee and Immigrants	1,575,161
U.S. Multi-City	His House, Inc	69,214
U.S. Multi-City	Heartland	330,046
U.S. Multi-City	Lutheran Immigration and Refugee Service	804,135
Staunton, VA	Shenandoah	980,112
Lincolndale, NY	Lincoln Hall	3,800,000
San Antonio, TX	St. Peter-St. Joseph Children's Home	1,704,925
Corpus Christi, TX	Upbring	643,276
Chicago, IL	Heartland Human Care, Inc	7,764,682
Chicago, IL	Heartland Human Care, Inc	693,934
National	United Stated Conference of Catholic Bishops	1,505,823
Mesa, AZ	A New Leaf	736,736
La Verne, CA	David & Margaret	1,539,365
Fullerton, CA	Florence Crittenton	3,018,997
Manvel, TX	Shiloh	1,273,395
Houston, TX	Catholic Charities Houston-Galveston	1,670,956
Miami, FL	His House	2,202,796
Corpus Christi, TX	Upbring	3,134,996
U.S. Multi-City	BCFS Health and Human Services (102)	24,469,448
National	Lutheran Immigration and Refugee Service	4,303,231
Alexandria, VA	Juvenile Detention Commission for Northern Virginia	631,569
Seattle, WA	Youth Care	384,560
Portland, OR	Morrison Child and Family Services	2,622,674
Phoenix, AZ	Tumbleweed Child and Family Services	525,600
Philadelphia, PA	KidsPeace	2,471,157
San Antonio, TX	BCFS Health and Human Services (110)	479,610
San Antonio, TX	Seton Home	804,614
Fairfield, CA	BCFS Health and Human Services (112)	937,867
Bristow, VA	Youth for Tomorrow	2,327,600
Bristow, VA	Youth for Tomorrow	657,800
Woodland, CA	Yolo County	699,306
Miami, FL	Catholic Charities Boystown	1,312,947
San Antonio, TX	BCFS Health and Human Services (116)	2,190,001
San Antonio, TX	BCFS Health and Human Services (116)	864,000
Bronx, NY	Cardinal McCloskey	439,392
Syosset, NY	Mercy First	1,528,461
Kingston, NY	Children's Home of Kingston	435,312
New York, NY	Lutheran Social Services of Metropolitan New York	1,095,782

Location	Grantee	Amount
New York, NY	Cayuga Home for Children DBA Cayuga Centers	5,404,388
New York, NY	Cayuga Home for Children DBA Cayuga Centers	1,052,501
New York, NY	Catholic Guardian Services	1,664,514
Yonkers, NY	Leake and Watts Services, Inc	1,804,974
Yonkers, NY	Leake and Watts Services, Inc	473,826
U.S. Multi-City	Southwest Keys, Inc	10,257,820
U.S. Multi-City	Southwest Keys, Inc	1,330,080

ORR is continuously monitoring its capacity to provide post-release services to the unaccompanied alien children in HHS custody. 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 post-release services program through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility of safe and timely release of Unaccompanied Alien 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.

Elizabeth Leo,

Grants Policy Specialist, Division of Grants Policy, Office of Administration, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2901]

Medical Devices; Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that it is necessary for manufacturers of certain reusable medical devices to include in their premarket notifications (510(k)s) instructions for use which have been validated and validation data regarding cleaning, disinfection, and sterilization, for which a substantial equivalence determination may be based. This notice includes a list of these reusable devices that will require validated instructions for use and validation data in their premarket notification. FDA is publishing this list in accordance with the requirements established by the 21st Century Cures Act. This action ensures that the premarket requirements for these device types are clear and predictable which facilitates more efficient review of these 510(k)s.

DATES: These actions are effective on August 8, 2017.

FOR FURTHER INFORMATION CONTACT: Constance Soves, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1437, Silver Spring, MD 20993–0002, 301–796–6951.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three categories (classes) of devices, based on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as post-amendments devices), are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA initiates one of the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i), to a predicate device that is already legally marketed. The Agency determines whether new devices are substantially equivalent to predicate devices through review of premarket notifications under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and its implementing regulations, codified in Title 21 of the Code of Federal Regulations (21 CFR part 807, subpart E), require persons who intend to market a new device that does not require a premarket approval application under section 515 of the FD&C Act (21 U.S.C. 360e) to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On December 13, 2016, the President signed into law the 21st Century Cures Act (Pub. L. 114–255) (Ref. 1). Section 3059 of the 21st Century Cures Act, in part, amends section 510 of the FD&C Act to require FDA to publish in the **Federal Register** a notice identifying a list of reusable device types that must include validated instructions for use and validation data regarding cleaning, disinfection, and sterilization in their 510(k) submissions. This section also