Dated: April 18, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2013–09651 Filed 4–23–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.676]

Announcement of the Award of 12 Single-Source Program Expansion Supplement Grants to Unaccompanied Alien Children's Shelter Care Grantees

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Announcement of the award of 12 single-source program expansion grants to 10 current grantees to expand bed capacity and supportive services to the increasing number of unaccompanied alien children.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of twelve single-source program expansion supplement grants to the following ten current grantees, for a total of $33,653,092.

Organization	Location	Amount
Children's Center, Inc	Galveston, TX	$354,377
BCFS Health and Human Services	San Antonio, TX	11,826,867
Heartland Human Care Services, Inc	Chicago, IL	1,459,119
Southwest Key, Inc	Austin, TX	12,450,000
United States Conference of Catholic Bishops	Washington, DC	300,000
Lutheran Immigration Refugee Services	Baltimore, MD	2,500,000
Lutheran Social Services of the South	Austin, TX	2,171,142
His House	Opa Locka, FL	950,000
Lincoln Hall	Lincolndale, NY	523,520
Youth For Tomorrow	Bristow, VA	1,118,067

These supplement grants will support the expansion of bed capacity and supportive services to meet the number of unaccompanied alien children referrals from the Department of Homeland Security (DHS). The funding program is mandated by section 462 of the Homeland Security Act to ensure appropriate placement of all referrals from the DHS. The program is tied to DHS apprehension strategies and sporadic number of border crossers. Award funds will support services to unaccompanied alien children through September 30, 2013.

DATES: The period of support under these supplements is October 1, 2012 through September 30, 2013.

FOR FURTHER INFORMATION CONTACT: Jallyn Sualog, Acting Director, Division of Children's Services, Office of Refugee Resettlement, 901 D Street SW., Washington, Telephone (202) 401–4997. Email:*jallyn.sualog@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION: Since the beginning of FY 13, the Unaccompanied Alien Children (UAC) program has seen a dramatic increase in the number of DHS referrals. The influx of border crossers referred by DHS has grown beyond anticipated rates and has resulted in the program needing a significant increase in the number of shelter beds and supportive services.

The UAC program has specific requirements for the provision of services to unaccompanied alien children. These grantee organizations are the only entities with the infrastructure, licensing, experience, and appropriate level of trained staff to meet the required service requirements and the urgent need for the expansion of services required to respond to unexpected arrivals of unaccompanied children. The program expansion supplement will support such services and alleviate the buildup of children waiting in border patrol stations for placement in shelter care.

Statutory Authority: Section 462 of the Homeland Security Act, (6 U.S.C. 279) and sections 235(c) and 235(d) of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, (8 U.S.C. 1232(c) and 1232(d)).

Eskinder Negash,

Director, Office of Refugee Resettlement.

[FR Doc. 2013–09699 Filed 4–23–13; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the regulations that provide protection for human subjects of clinical investigations conducted in support of applications or submissions to FDA for FDA-regulated products. The regulations provide protection of the rights, safety, and welfare of human subjects involved in research activities within FDA's jurisdiction.

DATES: Submit either electronic or written comments on the collection of information by June 24, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information of an existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Protection of Human Subjects; Informed Consent; Institutional Review Boards—21 CFR Parts 50 and 56 (OMB Control Number 0910—NEW)

Part 50 (21 CFR part 50) applies to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 50 is intended to protect the rights and safety of subjects involved in investigations filed with the FDA under sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 379e, and 381, respectively) and sections 351 and 354–360F of the Public Health Service Act.

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (see 21 CFR 50.20). In seeking informed consent, each subject must be provided with certain elements of informed consent. Those elements are listed in § 50.25. Informed consent shall be documented in writing as described in § 50.27.

An institutional review board (IRB) may approve emergency research without requiring the informed consent of all research subjects provided the IRB finds and documents that certain criteria are met as required in § 50.24. We estimate that about five times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the five yearly requests for IRB review under § 50.24, a particular IRB will take about an hour during each of three separate fully convened IRB meetings to review the request under § 50.24 (one meeting occurring after community consultation). The total annual reporting burden for IRB review of emergency research under § 50.24 is estimated at 15 hours (see table 1).

The information requested in the regulations for exception from the general requirements for informed consent for medical devices (21 CFR 812.47), and the information requested in the regulations for exception from the general requirements of informed consent in § 50.23, paragraphs (a) through (c), and (e), is currently approved under OMB control number 0910–0586. The information requested in the investigational new drug (IND) regulations concerning exception from informed consent for emergency research under § 50.24 is currently approved under OMB control number 0910–0014. In addition, the information requested in the regulations for IND safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans (21 CFR 320.31(d) and 312.32(c)(1)(ii) and (iv)) is currently approved under OMB control number 0910–0672.

Some clinical investigations involving children, although otherwise not approvable, may present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (see § 50.54). Certain clinical investigations involving children may proceed if the IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and when the Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, makes a determination that certain conditions are met (see § 50.54(b)).

The information requested for clinical investigations in children of FDA-regulated products is covered by the collections of information in the IND regulations (part 312 (21 CFR part 312), the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812), the IRB regulations (21 CFR 56.115), the food additive petition and nutrient content claim petition regulations (21 CFR 101.69 and 101.70), and the infant formula regulations (parts 106 and 107 (21 CFR parts 106 and 107)), all of which are approved by OMB. Specifically, the information collected under the IND regulations is currently approved under OMB control number 0910–0014. The information collected under the IDE regulations is currently approved under OMB control number 0910–0078. The information collected under the IRB regulations is currently approved under OMB control number 0910–0130. The information collected in food additive and nutrient content claim petitions is currently approved under OMB control number 0910–0381 (general requirements) and 0910–0016 (Form FDA 3503). The information collected under the infant formula regulations is currently approved under OMB control number 0910–0256 (general requirements) and 0910–0188 (infant formula recalls).

Part 56 (21 CFR part 56) contains the general standards for the composition, operation, and responsibility of an IRB that reviews clinical investigations regulated by FDA under sections 505(i) and 520(g) of the FD&C Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas,

food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 56 is intended to protect the rights and welfare of human subjects involved in such investigations.

The information collected under the IRB regulations, ''Protection of Human Subjects—Recordkeeping and Reporting Requirements for Institutional Review Boards (part 56)'', including the information collection activities in the provisions in § 56.108(a)(1) and (b), is currently approved under OMB control number 0910–0130. The information collected under the regulations for the registration of IRBs in § 56.106 is currently approved under OMB control number 0910–0279. The information collected for IRB review and approval for the IDE regulations (part 812) is currently approved under OMB control number 0910–0078. The information collected for premarket approval of medical devices (part 814 (21 CFR part 814)) is currently approved under OMB control number 0910–0231. The information collected under the regulations for IRB requirements for humanitarian use devices (part 814, subpart H) is currently approved under OMB control number 0910–0332. The information collected under the regulations for IRB review and approval of INDs (part 312) is currently approved under OMB control number 0910–0014.

This new collection of information is limited to certain provisions in part 50, subpart B (informed consent of human subjects), and part 56 (IRBs), not currently approved under the OMB control numbers referenced elsewhere in this document. Those new proposed collections of information in part 50 are §§ 50.24 (emergency research), 50.25 (elements of informed consent), and 50.27 (documentation of informed consent).

In part 56, those new proposed collections of information are in § 56.109(e) (IRB written notification to approve or disapprove research); § 56.109(f) (continuing review of research); § 56.113 (suspension or termination of IRB approval of research); § 56.120(a) (IRB response to lesser administrative actions for noncompliance); and § 56.123 (reinstatement of an IRB or institution).

In § 56.109(f), the amount of time an IRB spends on the continuing review of a particular study will vary depending on the nature and complexity of the research, the amount and type of new information presented to the IRB, and whether the investigator is seeking approval of substantive changes to the research protocol or informed consent document. For many studies, continuing review can be fairly straightforward, and the IRB should be able to complete its deliberations and approve the research within a brief period of time.

When an IRB or institution violates the regulations, FDA issues to the IRB or institution a noncompliance letter (see § 56.120(a)). The IRB or institution must respond to the noncompliance letter describing the corrective actions that will be taken by the IRB or institution. FDA estimates about five IRBs or institutions will be issued a noncompliance letter annually. We estimate that the IRB's or institution's response will take about 10 hours to prepare, with an estimated total annual burden of 50 hours.

To date, no IRB or institution has been disqualified by FDA under § 56.121. Therefore, no IRB or institution has been reinstated under § 56.123. For this reason, we estimate the annual reporting burden for one respondent only. We estimate a 5-hour burden per response, with an estimated total annual burden of 5 hours.

Those regulatory provisions in parts 50 and 56 not currently approved under certain OMB control numbers are shown in table 1.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
56.109(e) IRB Written Notification to Approve or Disapprove Research; 56.109(f) Continuing Review; 50.25 Elements of Informed Consent; and 50.27 Documentation of Informed Consent	6,000	40	240,000	1	240,000
50.24 Exception from Informed Consent for Emergency Research	5	3	15	1	15
56.113 Suspension or Termination of IRB Approval of Research	6,000	1	6,000	0.5 (30 minutes)	3,000
56.120(a) IRB Response to Lesser Administrative Actions for Noncompliance	5	1	5	10	50
56.123 Reinstatement of an IRB or Institution	1	1	1	5	5
Total					243,070

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09622 Filed 4–23–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0401]

Draft Guidance for Industry on Safety Considerations for Container Labels and Carton Labeling Design To Minimize Medication Errors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' The draft guidance focuses on safety aspects of the container label and carton labeling design for prescription drug and biological products. The draft guidance provides sponsors of new drug applications (NDAs), biologics licensing applications (BLAs), abbreviated new drug applications (ANDAs), and prescription drugs marketed without an approved NDA or ANDA with a set of principles and recommendations for ensuring that critical elements of product container labels and carton labeling are designed to promote safe dispensing, administration, and use of the product to minimize medication errors.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 24, 2013.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carol Holquist, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4416, Silver Spring, MD 20993–0002, 301–796–0171.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.'' In Title I of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), Congress reauthorized and expanded the Prescription Drug User Fee Act program for fiscal years (FYs) 2008 through 2012 (PDUFA IV). As part of the performance goals and procedures set forth in an enclosure to the letter from the Secretary of Health and Human Services referred to in section 101(c) of FDAAA, FDA committed to certain performance goals and procedures. (See *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm*). In that letter, FDA stated that it would use fees collected under PDUFA to implement various measures to reduce medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs. Among these measures, FDA agreed that by the end of FY 2010, after public consultation with academia, industry, other stakeholders, and the general public, the Agency would publish draft guidance describing practices for naming, labeling, and packaging drugs and biologics to reduce medication errors. On June 24 and 25, 2010, FDA held a public workshop and opened a public docket (Docket No. FDA–2010–N–0168) to receive comments on these measures.

This draft guidance document, which addresses safety achieved through the design of drug product container labels and carton labeling design, is the second in a series of three planned guidance documents to minimize risks contributing to medication errors. The first guidance focuses on minimizing risks with the design of drug product and container closure design (December 13, 2012, 77 FR 74196), and the third guidance will focus on minimizing risks with drug product nomenclature.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the Agency's current thinking on addressing safety achieved through drug product design to minimize medication errors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this draft guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov*.

Dated: April 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09640 Filed 4–23–13; 8:45 am]

BILLING CODE 4160–01–P