

**Registration:** Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by August 22, 2008. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Bernadette Kawaley (see *Contact Person*) at least 7 days in advance.

Submit written abstracts to the contact person by August 15, 2008 (see section II of this document for additional information).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA will explore the use of alternative methods for detecting mycoplasma contamination in the manufacture of vaccines, including pandemic influenza vaccines, and other biological products. Alternative methods that allow detection of mycoplasma in a shorter period, as compared to the current methods, could expedite the manufacture of vaccines and other biological products. The workshop is aimed at: (1) Identifying promising rapid method(s) for further validation to demonstrate equivalency or superiority to methods currently used for mycoplasma testing during the manufacture of vaccines and other biological products and (2) providing information that may lead to collaborative studies with FDA on testing for mycoplasma. The program agenda will be available at <http://www.fda.gov/cber/scireg.htm>, by September 5, 2008.

##### **II. Submission of the Abstracts**

For purposes of discussion at the workshop, FDA is requesting submission of abstracts that describe current developments in rapid methods for detection of mycoplasma contamination during manufacture of vaccines and other biological products. FDA will select a limited number of abstracts for formal presentation at the workshop by the abstract authors. If time permits, FDA may allow additional presentations from interested persons attending the meeting who did not submit an abstract. FDA will notify authors of abstracts accepted for presentation at the workshop by August 25, 2008.

Abstracts should be a maximum of 350 words, printed (typewritten or computer) and double-spaced. The title should be brief and capitalized. The authors name(s), contact information,

and agency, institution, or facility involved should be listed. The author who intends to present the abstract should submit a current curriculum vitae with the abstract.

Dated: July 11, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-16459 Filed 7-17-08; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-1995-N-0400 (formerly Docket No. 1995N-0245), FDA-1995-N-0029 (formerly Docket No. 1995N-0282), FDA-1995-N-0224 (formerly Docket No. 1995N-0347)]

##### **Small Entity Compliance Guide: Food Labeling; Nutrient Content Claims: Definition for "High Potency" and Definition of "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide (SECG) for a final rule published in the *Federal Register* of September 23, 1997, entitled "Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition of "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods." This SECG is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

**DATES:** Submit written or electronic comments on the SECG at any time.

**ADDRESSES:** Submit written comments on the SECG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs, Office of Nutrition, Labeling, and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301-436-2639. Send one self-addressed adhesive

label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

##### **FOR FURTHER INFORMATION CONTACT:**

Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2375.

##### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the *Federal Register* of September 23, 1997 (62 FR 49868), FDA issued a final rule amending its regulations to: Define the term "high potency" as a nutrient content claim; define nutrient content claims using the term "antioxidant" (e.g., "good source of antioxidants," "high in antioxidants," "more antioxidants") and to correct an omission pertaining to the use of "sugar free" claims on dietary supplements. This final rule became effective March 23, 1999.<sup>1</sup>

FDA examined the economic implementation of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-602) and determined that the final rule might have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the agency's current thinking on this subject. 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this SECG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The SECG and received

<sup>1</sup> FDA published a correction to the final rule in the *Federal Register* of October 24, 1997 (62 FR 55331). The correction was to correct a RIN number that appeared in the September 23, 1997, final rule.

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: July 10, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-16448 Filed 7-17-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Refugee Resettlement

#### Noncompetitive Urgent Single Source Unaccompanied Alien Children Trauma Initiative

**AGENCY:** Division of Unaccompanied Children's Services, Office of Refugee Resettlement, DHHS.

**ACTION:** Notice to Award a Noncompetitive Urgent Single Source Unaccompanied Alien Children Trauma Initiative.

CFDA#: 93.676.

**Legislative Authority:** Section 462 of the Homeland Security Act of 2002 (6 U.S.C. 279), which, in March 2003, transferred responsibility for the Unaccompanied Alien Children's Program from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of Office of Refugee Resettlement (ORR) within the Department of Health and Human Services (HHS).

**Amount of Award:** \$1,826,037.00.

**Project Period:** July 15, 2008–January 15, 2011.

**Summary:** Notice is hereby given that the Office of Refugee Resettlement's Division of Unaccompanied Children's Services (ORR/DUCS) will award a noncompetitive urgent single-source award to the Latin American Health Institute (LHI) to provide urgent care for unaccompanied alien children (UAC) in response to an unsolicited application.

ORR/DUCS-funded facilities currently have very limited capacity to help UAC

cope with potentially devastating consequences of trauma. Such limited trauma-informed services within the ORR/DUCS network of care puts UAC and the ORR/DUCS program at tremendous risk.

A great number of UAC have been subjected to severe trauma, including sexual abuse and sexual assault in their home countries or on their journey to the U.S.; gang violence; domestic violence; traumatic loss of a parent; and physical abuse and neglect. In addition, UAC experience the increased probability of ongoing trauma as a result of their uncertain legal status and return to difficult life circumstances. ORR/DUCS-funded facilities currently have very limited specifically targeted capacity to help UAC cope with the potentially devastating consequences of trauma.

Trauma affects children in very complex ways, including behavioral problems and potential involvement with the juvenile justice system; suicidal ideation and attempts; serious depression; and lasting delays in reaching emotional, cognitive, and interpersonal developmental milestones. ORR/DUCS-funded care providers are in a unique position to assist and intervene in these cases in order to minimize the harmful effects of past and possible ongoing trauma.

The lack of expertise in addressing trauma leaves the ORR/DUCS-funded care provider facilities staff particularly vulnerable to the occupational hazards of working with traumatized children, such as vicarious trauma, boundary violations with children, job burnout, and high staff turnover.

The youth workers in the ORR/DUCS-funded facilities do not have specific knowledge of childhood trauma and more importantly, they lack effective responses such that they are left ill-prepared to handle the complex needs of the UAC in their care. Without this type of expertise, staff in the facilities may in certain situations indirectly or unknowingly foster an environment that perpetuates trauma for the children. Trauma training will prepare care provider facility staff to better help UAC and to convey accurate information to their sponsors, thus creating safer outcomes for the youth and the communities where they are released. The LHI Unaccompanied Alien Children Trauma Initiative will provide specialized training in delivery of trauma-informed services, and identification of ways that promote mastery and resilience in trauma victims, based on proven expertise in child trauma and immigrant and refugee experience.

### FOR FURTHER INFORMATION CONTACT:

Maureen Dunn, Director, Division of Unaccompanied Children's Services, Office of Refugee Resettlement, 900 D Street, SW., Washington, DC 20047. e-mail: [Maureen.Dunn@acf.hhs.gov](mailto:Maureen.Dunn@acf.hhs.gov) and phone: 202-401-5523.

Dated: July 7, 2008.

**David H. Siegel,**

*Acting Director, Office of Refugee Resettlement.*

[FR Doc. E8-16573 Filed 7-17-08; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2008-0178]

#### Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers: 1625-0032, 1625-0037, 1625-0041 and 1625-0042

**AGENCY:** Coast Guard, DHS.

**ACTION:** Thirty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding four Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) requesting an extension of their approval for the following collections of information: (1) 1625-0032, Vessel Inspection Related Forms and Reporting Requirements Under Title 46 U.S. Code; (2) 1625-0037, Certificates of Compliance, Boiler/Pressure Vessel Repairs, Cargo Gear Records, and Shipping Papers; (3) 1625-0041, Various International Agreement Pollution Prevention Certificates and Documents, and Equivalency Certificates; and (4) 1625-0042, Requirements for Lightering of Oil and Hazardous Material Cargoes. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

**DATES:** Please submit comments on or before August 18, 2008.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2008-0178] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) or to OIRA. To avoid duplication,