

Transaction Publishers, Inc., 35 Berrue Circle, Piscataway, NJ 08854, *Officers:* Lori A. Fellmer, Secretary (Qualifying Individual), Mary E. Curtis, President.

Logistics Innovators, Inc., 16600 E. 33rd Drive, Unit 26, Aurora, CO 80011, *Officers:* Toni R. Brock, President (Qualifying Individual), Robert A. Brock, Secretary.

Vencel Colombia Corp., 106 14 Corona Ave., Corona Queens, NY 11368, *Officers:* Jason Fernandez, Operations Director (Qualifying Individual), David Fernandez, CEO.

Manray Express Freight Systems, Inc., 5959 N.W. 37th Ave., Miami, FL 33142, *Officer:* Robert E. Hamer, President (Qualifying Individual).

Damca International, LLC dba Blue Project Cargo, 1335 NW 98th Court, Ste. 1 & 2, Doral, FL 33172, *Officer:* Nils Ekman, President (Qualifying Individual).

A&A Contract Customs Brokers USA, Inc., dba A&A International Freight Forwarding, 2 12th Street, Blaine, WA 98230, *Officer:* Beau Rogers, Vice President (Qualifying Individual).

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants:

Q&C Global Corporation, 2112 San Antonio Dr., Montebello, CA 90640, *Officers:* Clay F. Wong, President (Qualifying Individual), Quan Li Smith, Vice President.

Geek Investments LLC, 1826 Rambling Rose Lane, Mishawaka, IN 46544, *Officer:* Patience Taruwinga, Member (Qualifying Individual).

GTO Autotrade Inc dba Global Trade Organization, 8113 NW 68th Street, Miami, FL 33166, *Officers:* Juan F. Sierra, President (Qualifying Individual), Luz M. Arango, Vice President.

Min American Inc., 11357 Nuckols Road, Ste. 200, Glen Allen, VA 23059, *Officer:* Gina M. Cianelli, CEO (Qualifying Individual).

Waled International, LLC, 319 Nadia Way, Stafford, TX 77477, *Officer:* Abdurahman Esmael, Member/Manager (Qualifying Individual).

Dated: August 31, 2009.

**Karen V. Gregory,**  
*Secretary.*

[FR Doc. E9-21331 Filed 9-3-09; 8:45 am]

BILLING CODE 6730-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Chronic Fatigue Syndrome Advisory Committee

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will hold a meeting. The meeting will be open to the public.

**DATES:** The meeting will be held on Thursday, October 29, 2009, and Friday, October 30, 2009. The meeting will be held from 9 a.m. until 5 p.m. on both days.

**ADDRESSES:** Department of Health and Human Services; Room 800, Hubert H. Humphrey Building; 200 Independence Avenue, SW., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Wanda K. Jones, Dr.P.H.; Executive Secretary, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services; 200 Independence Avenue, SW., Hubert Humphrey Building, Room 712E; Washington, DC 20201; (202) 690-7650.

#### SUPPLEMENTARY INFORMATION:

CFSAC was established on September 5, 2002. The Committee was established to advise, consult with, and make recommendations to the Secretary, through the Assistant Secretary for Health, on a broad range of topics including (1) The current state of the knowledge and research about the epidemiology and risk factors relating to chronic fatigue syndrome, and identifying potential opportunities in these areas; (2) current and proposed diagnosis and treatment methods for chronic fatigue syndrome; and (3) development and implementation of programs to inform the public, health care professionals, and the biomedical, academic, and research communities about advances in chronic fatigue syndrome.

The agenda for this meeting is being developed. The agenda will be posted on the CFSAC Web site, <http://www.hhs.gov/advcomcfs>, when it is finalized. In addition, the meeting will be WebCast. Details will be posted to the CFSAC Web site as they become available.

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into

the building where the meeting is scheduled to be held. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Members of the public will have the opportunity to provide comments at the meeting. Individuals who wish to address the Committee during the public comment session must pre-register by October 14, 2009. Any individual who wishes to participate in the public comment session should call the telephone number listed in the contact information or send an e-mail to [cfsac@hhs.gov](mailto:cfsac@hhs.gov) to register. Public comments will be limited to five minutes per speaker.

Members of the public who wish to have printed material distributed to CFSAC members for discussion should submit, at a minimum, one copy of the material to the Executive Secretary, CFSAC, prior to close of business on October 15, 2009. Submissions are limited to five typewritten pages. Contact information for the Executive Secretary is listed above.

Dated: August 20, 2009.

**Wanda K. Jones,**

*Executive Secretary, CFSAC.*

[FR Doc. E9-21334 Filed 9-3-09; 8:45 am]

BILLING CODE 4150-42-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Child Care and Development Fund Annual Aggregate Report—ACF-800.

*OMB No.:* 0970-0150.

*Description:* Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101-508, 42 U.S.C. 9858) requires that States and Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Annual aggregate reports include data elements represented in the ACF-800 reflecting the scope, type, and methods of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and

regulations, ACF requests extension of the ACF-800. With this extension, ACF is proposing several changes and

clarifications to the reporting requirements and instructions.  
*Respondents:* States, the District of Columbia, and Territories including

Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-800 .....	56	1	40	2,240

Estimated Total Annual Burden Hours: 2,240

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 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. E-mail 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, Fax: 202-395-7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: September 1, 2009.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. E9-21410 Filed 9-3-09; 8:45 am]

BILLING CODE 4184-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2009-N-0098]

##### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of Potential Data Sources for the Sentinel Initiative

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 5, 2009.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and title, "Evaluation of Potential Data Sources for the Sentinel Initiative." Also include the FDA docket number found in brackets in the heading of this document.

##### FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794, [JonnaLynn.Capezzuto@fda.hhs.gov](mailto:JonnaLynn.Capezzuto@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

##### Evaluation of Potential Data Sources for the Sentinel Initiative

In September 2005, the Secretary of Health and Human Services (the Secretary) asked FDA to expand its current system for monitoring medical product performance. The Secretary asked FDA to explore the possibility of working in collaboration with multiple healthcare data systems to augment FDA's capability of identifying and evaluating product safety information beyond its existing voluntary reporting systems. Such a step would strengthen FDA's ability, ultimately, to monitor the performance of a product after marketing approval. The Secretary recommended that FDA explore creating a public-private collaboration as a

framework for such an effort leveraging increasingly available large, electronic healthcare databases and taking advantage of emerging technologies and building on existing systems and efforts, rather than creating new systems.

In 2006, the Institute of Medicine (IOM) issued a report entitled "The Future of Drug Safety—Promoting and Protecting the Health of the Public."<sup>1</sup> Among other suggestions, this IOM report recommended FDA identify ways to access other health-related databases and create a public-private partnership to support safety and efficacy studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007<sup>2</sup> (FDAAA). Section 905 of FDAAA calls for the Secretary to develop methods to obtain access to disparate data sources and to establish an active postmarket risk identification and analysis system that links and analyzes healthcare data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities. FDA views the Sentinel Initiative as a mechanism through which this mandate can be carried out.

Consistent with FDA's mission to protect and promote the public health, FDA is embarking on the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the post-market performance of a product. As currently envisioned, the Sentinel Initiative will enable FDA to capitalize on the capabilities of multiple, existing data systems (e.g. electronic health record systems and medical claims databases)

<sup>1</sup> Institute of Medicine, "The Future of Drug Safety—Promoting and Protecting the Health of the Public," September 22, 2006, <http://www.iom.edu/>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

<sup>2</sup> Food and Drug Administration Amendments Act of 2007, Public Law 110-85, was signed into law in September 2007. See Title IX, Section 905.