

Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. E7-17139 Filed 8-28-07; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR part 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicant

Jeepney Express Padala, Inc. dba Jeepney Express; Kalesa Express; Victory Cargo, 2647 West Woodland Drive, Anaheim, CA 92801. Officers: Edna Cabal Quinto, Treasurer (Qualifying Individual), Gregorio Sycip, President.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicant

One Arrow, LLC, 12900 Griffing Blvd., Miami, FL 33161. Officer: Emmanuel Nwankwo, President (Qualifying Individual).

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicant

Victoria Shipping, 104 Bald Knob Road, Wetumpka, AL 36092. Susan V. Hagan, Sole Proprietor.

Dated: August 24, 2007.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. E7-17128 Filed 8-28-07; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) announces the following meeting of the aforementioned committee.

Times and Dates: 2 p.m.–5:30 p.m., September 17, 2007. 8:30 a.m.–2 p.m., September 18, 2007.

Place: NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

Status: Open to the public, and limited only to the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters To Be Discussed: The agenda will include welcome remarks by the Director, NCHS; introduction of new chair and new members and key NCHS staff; data access discussions; discussion of the upcoming review of the SLAITS program; discussion of upcoming program reviews and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by September 10, 2007.

The agenda items are subject to change as priorities dictate.

For Further Information Contact: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458-4500, fax (301) 458-4020.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 22, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7-17137 Filed 8-28-07; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0420]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Orphan Drugs” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 29, 2007 (72 FR 29515), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0167. The approval expires on August 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-17094 Filed 8-28-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0310]

Companion to Guidance for Industry on Pharmacogenomic Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a draft guidance entitled "Pharmacogenomic Data Submissions—Companion Guidance." The guidance is intended as a companion to the guidance of the same name, which was issued in 2005 (70 FR 14698; March 23, 2005). It reflects experience gained since the issuance of that guidance with voluntary genomic data submissions as well as with review by FDA of numerous protocols and data submitted under investigational new drug (IND) applications, new drug applications (NDAs), and biologics license applications (BLAs). The recommendations are intended to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 27, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Federico Goodsaid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3663, Silver Spring, MD 20903-0002, 301-796-1535.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance, which is intended to be used as a companion to the guidance issued in March 2005 entitled "Pharmacogenomic Data Submissions." This draft guidance entitled "Pharmacogenomic Data Submissions—Companion Guidance" is based on FDA's experience with voluntary genomic data submissions as well as

with its review of numerous protocols and data submitted under IND applications, NDAs, and BLAs during the last 2 years. FDA believes that the recommendations in the draft guidance will benefit sponsors considering the submission of either voluntary genomic data or marketing submissions containing genomics data. As technology changes and more experience is gained, these recommendations may be updated.

Specifically, this draft guidance contains recommendations on gene expression data from microarrays, genotyping, genomic data in clinical study reports, genomic data from nonclinical toxicology studies, and data submission formats. Each of the sections in the guidance make recommendations on technical steps or describes report contents or formats that will facilitate the submission of genomic data to FDA. A concept paper containing the contents of this draft guidance was made available on the Genomics Web site of FDA (http://www.fda.gov/cder/genomics/conceptpaper_20061107.pdf) on November 2006. The concept paper was discussed at the FDA/Drug Information Association/Pharmaceutical Research and Manufacturers of America Foundation/Biotechnology Industry Organization workshop on Best Practices and Development of Standards for the Submission of Genomic Data to FDA held in Washington, DC on November 27 and 28, 2006. This draft companion guidance reflects feedback received at and since the workshop.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommendations for the submission and review of genomic data. 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 document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-17103 Filed 8-28-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0125]

Draft Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 9, 2007 (72 FR 37246). The document announced the availability for public comment of a draft guidance entitled "Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims." The document was published with an incorrect Internet address for submitting electronic comments and an incorrect telephone number. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT:

Paula Trumbo, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2579.

SUPPLEMENTARY INFORMATION: In FR Doc. E7-13274, appearing on page 37246 in the **Federal Register** of Monday, July 9, 2007, the following corrections are made:

1. On page 37246, in the second column, in the **ADDRESSES** section, the phrase "<http://www.fda.gov/dockets/ecomments>" is corrected to read "<http://www.fda.gov/dockets/ecomments>".

2. On page 37246, in the second column, in the **FOR FURTHER INFORMATION CONTACT** section, the telephone number "310-436-2579" is corrected to read "301-436-2579".