

## 8. Other Business

Federal Communications Commission.

**Roderick Porter,***Acting Chief, International Bureau.*

[FR Doc. 05-20614 Filed 10-18-05; 8:45 am]

BILLING CODE 6712-01-P

**FEDERAL MARITIME COMMISSION****Notice of Agreement Filed**

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's Office of Agreements (202-523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov)).

*Agreement No.:* 011488-002.*Title:* CSAV/Lauritzen Reefers Space Charter Agreement.*Parties:* CSAV Sud Americana de Vapores S.A. and LauritzenCool AB.*Filing Party:* Wayne R. Rohde, Esq., Sher & Blackwell LLP, 1850 M Street, NW., Suite 900, Washington, DC 20036.*Synopsis:* The amendment changes LauritzenCool AB to NYKLauritzenCool AB in the agreement, changes the agreement name, and republishes the agreement.

Dated: October 14, 2005.

By Order of the Federal Maritime Commission.

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

[FR Doc. 05-20914 Filed 10-18-05; 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. app. 1718 and 46 CFR 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 Applicants**

Ameroasia Int'l, 1315 Magnolia Avenue, #3, Gardena, CA 90247. *Officer:* Jun Yin, President (Qualifying Individual).

West Point Relocation, 10505 Glenoaks Blvd., Pacoima, CA 91331. *Officer:* Elo Chhen, President (Qualifying Individual).

Hoyer Global (USA), Inc., 16055 Space Center Blvd., Suite 500, Houston, TX 77062. *Officers:* Ylna Flores, Secretary (Qualifying Individual), Cor Mol, CEO.

Embarque Puerto Plata, Inc., 1426 Cromwell Avenue, Bronx, NY 10452. *Officers:* Estebaldo Garcia, President (Qualifying Individual), Hyde Garcia, Vice President.

S.F. Systems Ltd., 167-10 South Conduit Avenue, Suite 205, Jamaica, NY 11434. *Officer:* Richard Shifu Lin, President, (Qualifying Individual).

NEX Worldwide Express Inc., 267 Fifth Avenue, Suite B-1, New York, NY 10016, *Officers:* Hasan Akipek, Secretary (Qualifying Individual), Kayhan Ozcilingir, President.

Zenith Logistic (USA) Inc., 67-39 165 Street, Fresh Meadows, NY 11356. *Officers:* Xiao Jun He, Vice President (Qualifying Individual).

Advanced Courier Express (ACE), Ltd., dba Hanjin Express NY, JFK International Airport Bldg. #9, Suite #14, Jamaica, NY 11430. *Officer:* Byung Min Kim, President (Qualifying Individual).

Colorado International Transportation Company, 541 East Cimarron Street, Colorado Springs, CO 80903. *Officers:* Anthony T. Marulli, Treasurer (Qualifying Individual), Edward Sobczewski, President.

MTM International Logistics LLC, 9725 NW 52nd Street, Suite #118, Miami, FL 33178. *Officers:* Guillermo Sigfrido Carbi Haubold, Manager (Qualifying Individual), Mariano Banez Perez, Manager.

Prodemeca Corp., 4744 NW 114th Avenue, Suite #202, Doral, FL 33178. *Officers:* Michael Tomasicchio, President (Qualifying Individual), Michele Tomasicchio, President.

Amilcar Rene Estrada dba Transportes Estrada, 7400 #B Harry Hines Blvd., Dallas, TX 75235, *Officer:* Amilcar Bene Estrada, Owner (Qualifying Individual).

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

J.M.S. Logistics Corp., 6611 NW 84 Avenue, Miami, FL 33166. *Officer:*

Soraima I. Martinez, President (Qualifying Individual).

Intercargo Express, 10911 Dennis Road, #405, Dallas, TX 75229. Reyna Isabel Bleeker, Sole Proprietor.

Allen Lund Company, Inc., 4529 Angeles Crest Highway, #300, La Canada, CA 91011. *Officer:* Robert R. Bush, Manager (Qualifying Individual).

**Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants**

AM Worldwide, Inc., 2928-B Greens Road, Suite 450, Houston, TX 77032. *Officers:* Anthony Mello, President (Qualifying Individual) Kimberly Mello, Vice President.

Guempel Lynnwood Corporation dba Galaxsea, Freight Forwarding, 13024 Beverly Park Road, Suite 101, Mukilteo, WA 98275. *Officers:* Terrina R. Guempel, President (Qualifying Individual), John Guempel, Vice President.

All-in-One Shipping, Inc., 8358 West Oakland Park Blvd. Suite 203g, Sunrise, FL 33351. *Officer:* Joshua Sean Morales, President (Qualifying Individual).

FM Shipping, 26542 Soteio Street, Mission Viejo, CA 92692. *Officers:* Imad Farah, President (Qualifying Individual), Raed Mashaqi, Vice President.

BF International Inc., 3080 North Rield Place, Suite 109, Roswell, GA 30076. *Officers:* Markos Baghoasarian, President (Qualifying Individual), Edgar Bagdosaryan, Vice President.

Kimmel Worldwide Logistics, L.L.C., 46 Haywood Street, Suite #215, Asheville, NC 28801. *Officers:* Tylene Kay Ashcroft, Vice President (Qualifying Individual), Paul J. Samuels, President.

Gunhill Shipping, 1444 E. Gunhill Road, Bronx, NY 10469. *Officer:* Dave Stewart, President (Qualifying Individual).

Active Shipping of New York, Inc., 178-28 Jamaica Avenue, Jamaica, NY 11432. *Officers:* Rohan Moonisar, Vice President (Qualifying Individual), Tara B. Ramnath, President.

Omega Forwarding Group LLC, 18860 Woodfield Road, Unit C, Gaithersburg, MD 20879. *Officers:* Raguel Fazio, Export Manager (Qualifying Individual), Pablo Yanez, President.

Transcarveca USA Corp., 8375 N.W. 68th Street, Miami, FL 33166. *Officer:* Luis Alberto Fuenmayor, President (Qualifying Individual).

Dated: October 14, 2005.

**Karen V. Gregory,**

*Assistant Secretary.*

[FR Doc. 05-20913 Filed 10-18-05; 8:45 am]

BILLING CODE 6730-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for "The Centers for Education and Research on Therapeutics (CERTs)," are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

*SEP Meeting on:* The Centers for Education and Research on Therapeutics (CERTs).

*Date:* November 2-3, 2005 (Open on November 2 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting).

*Place:* John M. Eisenberg Building, AHRQ Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

*Contact Person:* Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville,

Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: October 07, 2005.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 05-20937 Filed 10-18-05; 8:45 am]

BILLING CODE 4160-90-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003D-0367]

#### Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications." This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling using the electronic common technical document (eCTD) specifications. The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800-835-4709 or 301-827-1800. Submit written comments on the 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 <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, e-mail: [levinr@cder.fda.gov](mailto:levinr@cder.fda.gov), or Robert Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications." This document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional labeling) in electronic format based on the International Conference on Harmonisation eCTD specifications.

In the **Federal Register** of August 29, 2003 (68 FR 52044), FDA made available a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions" and gave interested persons an opportunity to submit comments by October 28, 2003. The agency considered received comments as it finalized this guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on providing applications and related submissions in electronic format. 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