

Dated: June 1, 2007.

Bryant L. VanBrakle,
Secretary.

[FR Doc. E7-10896 Filed 6-5-07; 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 Applicants

CNF International, Inc., 550 E. Carson Plaza Drive, #112, Carson, CA 90746.
Officers: Paul Wang Lee, President (Qualifying Individual), Mi Ran Lee, Secretary.

Evangel Shipping, Inc., 10408 Daines Drive, Temple City, CA 91780.
Officer: Xiujuan Lai, CEO (Qualifying Individual).

Champ International Shipping, Inc., 900 Kaighns Avenue, Camden, NJ 08104.
Officer: Roy Barrington Hibbert, President (Qualifying Individual).

Cargois Inc., 2700 Coyle Avenue, Elk Grove Village, IL 60007. *Officers:* Souck-Sin Lee, Treasurer (Qualifying Individual), Jong Han Kwon, President.

Best Shipping Ever, Inc., 734 Grand Avenue, Unit C, Ridgefield, NJ 07657.
Officer: Young S. Kim, President, (Qualifying Individual).

Golden Sea USA Inc., 155-06 So. Conduit Ave., Suite 200, Jamaica, NY 11434. *Officers:* Zhang, Shen, Vice President, (Qualifying Individual), Xia Fang, President.

Dyna Logistics Inc., 2415 S. Sequoia Drive, Compton, CA 90220. *Officers:* Alfie Chi-Yang, Director (Qualifying Individual), Michelle Yang, Director/Secretary.

Siboney Shipping LLC, 10943 NW 122 Street, Medley, FL 33178. *Officer:* Kaye Graham, Owner (Qualifying Individual).

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

AHC Logistics Cargo Consultant, Inc., 11591 NW 50th Terrace, Doral, FL 33178. *Officers:* Alberto Jose Hernandez Crassus, President (Qualifying Individual), Amy Aracely Vega, Vice President.

Express International Cargo, Corp., dba Express Ocean Services, 7220 NW 36 Street, Suite 300, Miami, FL 33166.
Officer: Carlos Adolfo Marzol, President (Qualifying Individual).

Salviati and Santori Enterprises Inc., 10 East Merrick Road, Suite 200, Valley Stream, NY 11580. *Officers:* Richard Cazan-Cassini, Exec. Vice Pres. (Qualifying Individual), Francesco Santori, President.

IPPCO Global Services, Inc., 14589 Industry Circle, La Mirada, CA 90637.
Officers: John W. Gamble, III, Secretary (Qualifying Individual), Dina T. Gamble, President.

Advanced Maritime Transports, Inc. dba AMT, 16800 Greenspoint Park Drive, Suite 170N, Houston, TX 77030.
Officers: William E. Netzing, III, President (Qualifying Individual), Alain Vedrines, Director.

Dated: June 1, 2007.

Bryant L. VanBrakle,
Secretary.

[FR Doc. E7-10899 Filed 6-5-07; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substance and Disease Registry; The Health Department Subcommittee of the Board of Scientific Counselors, CDC, National Center for Environmental Health (NCEH)/Agency for Toxic Substances and Disease Registry (ATSDR): Teleconference Meeting

Notice of Cancellation: This notice was published in the **Federal Register** on May 4, 2007, Volume 72, Number 86, page 25318. The meeting previously scheduled to convene on June 4, 2007 has been cancelled.

Contact Person for More Information: Shirley D. Little, Committee Management Specialist, NCEH/ATSDR, 1600 Clifton Road, Mail Stop E-28, Atlanta, GA 30303; telephone 404/498-0615, fax 404/498-0059; E-mail: slittle@cdc.gov.

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: May 30, 2007.

Elaine L. Baker,

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

[FR Doc. E7-10880 Filed 6-5-07; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000E-1253]

Determination of Regulatory Review Period for Purposes of Patent Extension; RAPLON

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RAPLON and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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/ecommments>.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period

forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product RAPLON (Rapacuronium Bromide). RAPLON is indicated as an adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgical procedures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for RAPLON (U.S. Patent No. 5,418,226) from Akzo Nobel N.V., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of RAPLON represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for RAPLON is 1,724 days. Of this time, 1,304 days occurred during the testing phase of the regulatory review period, while 420 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* November 30, 1994. The applicant claims October 31, 1994, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was November 30, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 25, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for RAPLON (NDA 20-984) was initially submitted on June 25, 1998.

3. *The date the application was approved:* August 18, 1999. FDA has verified the applicant's claim that NDA 20-984 was approved on August 18, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 126 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 6, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 3, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7-10853 Filed 6-5-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0215]

Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 30, 2007, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2007N-0215—Thiazolidinedione" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on July 23, 2007. All comments will be posted without change, including any personal information provided. Comments received on or before July 23, 2007, will be provided to the committee before the meeting.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel telephone number is 301-948-8900.

Contact Person: Cathy A. Miller, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1099), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: Cathy.Miller1@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512536 and 3014512535. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously