Maersk Sealand

Synopsis: The proposed agreement modification deletes the United States Australasia Agreement as a party to the agreement, changes the agreement name to the United States/Australasia Discussion Agreement, and deletes the Pacific Islands from the geographic scope. The amendment breaks Article 5.1(a) into two sub-paragraphs and revises the language of various sub-paragraphs to clarify the authority contained in the agreement. New sub-paragraphs 5.1(c) and 5.1(d) authorize agreement and multi-carrier service contracts. The parties are deleting the reference to conferences in Article 7, adding voting procedures for agreement service contracts and amendments in Article 8, and deleting Article 11 authorizing Independent Action. The amendment also makes technical corrections required by Australian law to Appendix B.

Agreement No.: 011435–007.

Title: APL/TMM/Lykes Space Charter Agreement.

Parties:

American President Lines, Ltd.—APL Co. Pte Ltd.,
TMM Lines Limited, LLC,
Lykes Lines Limited, LLC.

Synopsis: The amendment narrows the agreement's geographic scope and revises the agreement's authority and duration; the amendment also re-states the agreement.

Agreement No.: 011845.

Title: CCNI/Lykes Slot Charter Agreement.

Parties:

Compania Chilena de Navegacion Interoceanica S.A.
Lykes Lines Limited, LLC.

Synopsis: The agreement would authorize CCNI to charter space from Lykes on the latter's vessels in the trade between Port Everglades, Florida and Puerto Rico, on the one hand, and ports in Costa Rica, Guatemala, the Dominican Republic, and Colombia, on the other hand, and engage in cooperative activities related to such charter. Expedited Review is requested.

Agreement No.: 011846.

Title: CCNI/Maruba Cooperative Working Agreement.

Parties:

Compania Chilena de Navegacion Interoceanica S.A.
Empresa Maruba S.C.A.

Synopsis: The agreement permits the parties to charter vessels and vessel space to each other in the trade between the Pacific Coast of the United States and the Pacific Coast of Central and South America, on the one hand, and East and South Asia, on the other. It also authorizes the parties to enter into cooperative working agreements concerning the space chartering.

By Order of the Federal Maritime Commission.

Dated: March 14, 2003.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–6605 Filed 3–18–03; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 2, 2003.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. The Troy Savings Bank Employee Stock Ownership Plan, Troy, New York; to acquire voting shares of Troy Financial Corporation, Troy, New York, and thereby indirectly acquire voting shares of Troy Savings Bank, Troy, New York.

B. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. Richmond Community Hospital Foundation, Richmond, Virginia; to acquire voting shares of Consolidated Bank & Trust Company, Richmond, Virginia.

Board of Governors of the Federal Reserve System, March 13, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–6486 Filed 3–18–03; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–52]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210. CDC is requesting an emergency clearance for this data collection with a two week public comment period. CDC is requesting OMB approval of this package 7 days after the end of the public comment period.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 14 days of this notice.

Proposed Project: Select Agent Distribution Activity—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

Background

This project is designed to provide a systematic and consistent mechanism to review requests that come to CDC for Select Agents. In light of current Bioterrorism concerns and the significant NIH grant monies being directed toward Select Agent research, NCID anticipates the receipt of hundreds of requests for Select Agents. Applicants will be expected to complete an application form in which they will

identify themselves and their institution, provide a CV or biographical sketch, a summary of their research proposal, and sign indemnification and material transfer agreement statements. A user fee will be collected to recover costs for materials, handling and shipping (except for public health laboratories.) The cost to the respondent will vary based on which agent is requested.

Respondents	No. of respondents	No. of responses per respondent	Average burden per Response (in hours)	Total burden (in hours)
Researcher	900	1	30/60	450
Total				450

Dated: March 13, 2003.

Thomas Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–6504 Filed 3–18–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0419]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRECEDEX 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 PRECEDEX (dexemedetomidine). PRECEDEX is indicated for sedation of adult patients in the intensive care unit setting. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRECEDEX (U.S. Patent No. 4,910,214) from Orion Corp., 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, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PRECEDEX represented the first permitted commercial marketing or use of the product. 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 PRECEDEX is 3,894 days. Of this time, 3,529 days occurred during the testing phase of the regulatory review period, while 365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: April 21, 1989. The applicant claims March 27, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 21, 1989, 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 of the act*: December 18, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for PRECEDEX (NDA 21–038) was initially submitted on December 18, 1998.

3. *The date the application was approved*: December 17, 1999. FDA has verified the applicant's claim that NDA 21–038 was approved on December 17, 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 3,919 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 19, 2003. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for