passengers sailing on the M/V Meridian. The initial term of the Agreement extends through June 23, 1997.

Agreement No.: 224–201024
Title: Philadelphia Regional Port Authority/Delaware River Stevedores, Inc., Berthing Agreement
Parties:
Philadelphia Regional Port Authority
Delaware River Stevedores, Inc.
Synopsis: Under the proposed agreement, the port authority will provide berthing for a vessel and space to Delaware River Stevedoring at the Tioga Marine Terminal for the embarking and discharging of passengers and the parking for passengers' vehicles. The term of the agreement is from June 3, 1997 through June 17, 1997.

By Order of the Federal Maritime Commission.

Dated: May 23, 1997.

Joseph C. Polking,

Secretary.

[FR Doc. 97–14033 Filed 5–28–97; 8:45 am]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 13389–90, dated March 20, 1997) is amended to reflect the merger of the Office of Public Affairs and the Office of Health Communication, Centers for Disease Control and Prevention (CDC) and the establishment of the Office of Communication.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete the title and functional statement for the *Office of Public Affairs (CA2).*

Delete the title and functional statement for the *Office of Health Communication (CA3)* and insert the following.

Office of Communication (CA3). (1) Establishes, administers, and coordinates CDC's health communication and media relations policies in a manner to ensure that health communication efforts reflect the scientific integrity of all CDC research, programs, and activities, and that such information is factual, accurate, and targeted toward improving public heath; (2) plans, organizes, administers, and, when appropriate, implements CDC's communication programs consistent with policy direction established by the Department of Health and Human Services (DHHS); (3) provides leadership in the development of CDC's priorities, strategies, and practices for effective health communication and media relations; (4) provides a CDC-wide forum for the discussion, development, and adoption of health communication and media relations policies and procedures; (4) provides for the policy review and clearance of informational communication materials and media materials including press releases, press kits, talking points, and fact sheets; (6) provides the public, through information and media channels, access to information systems, services, and materials that support or promote the health of individuals and communities; (7) provides the mass media with access to subject matter experts, reports, and publications; (8) plans, coordinates, and conducts projects related to CDC-wide events and information programs for CDC personnel; (9) promotes, stimulates, conducts, and supports research on health communication topics of CDC-wide interest; (10) assists and supports the Centers, Institute, and Offices (CIOs) of the agency in conducting formative, process, and outcome research and evaluation in specific applications of health communication to program areas; (11) assists the CIOs and their constituents in identifying and building needed expertise and state-of-the-art technology, logistical support, and other capacities required for effective health communication and media relations; (12) promotes quality assurance in health communication programs, products, and initiatives; (13) systematically captures, assesses, and disseminates information on health communication research results and current or emerging trends and issues; (14) maintains liaison with officials from DHHS, other Federal and State public health agencies, and non-profit and voluntary health agencies to coordinate communication programs of mutual interest and concern; (15) creates and maintains liaison with CIOs to share information about health communication programs and media relations, encouraging and providing opportunities for CDC-wide collaboration; (16) coordinates implementation of the Freedom of Information Act for CDC.

Office of the Director (CA31). (1) Advises the Director, CDC, and the CIO's on all matters related to health communication and media relations; (2) ensures that CDC communication activities follow policy directions established by the Assistant Secretary for Public Affairs (HHS); (3) develops and coordinates CDC-wide policies and plans for health communication and media relations; (4) provides leadership in the development of CDC's priorities, strategies, and practices for effective communication activities; (5) manages the implementation of the Freedom of Information Act for CDC; (6) manages periodic CDC-wide events; (7) manages DHHS required clearances for CDC communication products; (8) produces periodic reports and publications; (9) provides writer-editor and other technical services to OC Divisions and CDC/OD regarding media and public relations communication; (10) manages CDC communication services to the public; (11) maintains liaison with officials of other Federal agencies, voluntary health agencies, and State agencies to coordinate communication programs of mutual concern.

Division of Health Communication (CA32). (1) Provides leadership in the development of CDC policy, principles, strategies, and practices for effective health communication; (2) provides a CDC-wide forum for the development of health communication policies and procedures; (3) promotes, stimulates, supports, and conducts research on topics of CDC-wide interest in health communication; (4) assists CIO's in conducting health communication research by providing consultation and access to information, expertise, and related services; (5) promotes, stimulates, and supports evaluation of the effort, efficiency, and effectiveness of health communication initiatives; (6) assists CIO's and their constituents in identifying and building needed expertise, state-of-the-art technology, and logistical support; (7) assists CIO's and their constituents in the planning, design, implementation, and evaluation of health communication initiatives; (8) systematically captures, assesses, and disseminates information on ongoing research, current trends, and emerging issues in health communication; (9) identifies and fosters collaboration with public, non-profit, and private organizations involved with health communication; (10) creates and maintains liaison with CIO's, staff offices, and other HHS agencies to share information about health communication activities and identify,

promote and implement collaborative efforts.

Divison of Media Relations (CA33). (1) Provides leadership through the development of policies and practices for effective communication through the media; (2) develops strategies for the Director, CDC, and other CDC leaders in developing and disseminating information through the media; (3) coordinates the development and dissemination of media information among CIO's and between CDC and HHS; (4) assists CIO's in meeting their press-related needs and priorities; (5) provides training and technical assistance to CDC staff about media relations; (6) provides advice and consultation to the Director and oversight of crosscutting issues related to communication; (7) provides the central point of contact to CDC for media representatives; (8) provides timely, thorough, and appropriate responses to inquiries by media representatives; (9) employs the latest technologies to serve CDC and media constituents best; (10) conducts special activities to develop relationships with media representatives; (11) periodically assesses the conduct of CDC media relations activities, including feedback from consumers.

Dated: May 15, 1997.

David Satcher,

Director.

[FR Doc. 97–13965 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0108]

Determination of Regulatory Review Period for Purposes of Patent Extension; PATANOL™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PATANOL™ 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 Commissioner 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 PATANOL™ (olopatadine hydrochloride). PATANOL™ is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PATANOL™ (U.S. Patent No. 5,116,863) from Alcon Laboratories, Inc., 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 1, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PATANOL™ 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 PATANOL™ is 1,064 days. Of this time, 739 days occurred during the testing phase of the regulatory review period, while 325 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 (21 U.S.C. 355(i)) became effective*: January 21, 1994. The applicant claims January 20, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 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 Federal Food, Drug, and Cosmetic Act*: January 29, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for PATANOL™ (NDA 20–688) was initially submitted on January 29, 1996.

3. *The date the application was approved*: December 18, 1996. FDA has verified the applicant's claim that NDA 20–688 was approved on December 18, 1996.

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 571 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 28, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 25, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management