certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's notice on small entities, small entity is defined as: (1) A small business; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's notice on small entities, we are certifying that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on small entities subject to the rule. Today's notice is specifically intended to be de-regulatory and to reduce, not increase, the paperwork and related burdens of the RCRA hazardous waste program. For businesses in general, including all small businesses, the changes would reduce the labor time and other costs of preparing, keeping records of, and submitting reports to the agency. The notice also reduces the frequency by which businesses must conduct specified recordkeeping and reporting activities. It also eliminates recordkeeping and reporting requirements, thereby streamlining facilities' compliance activities. Finally, the rule increases flexibility in how waste handlers may comply with the regulations. We therefore conclude that today's notice relieves regulatory burden for small entities. We continue to be interested in the potential impacts of the notice on small entities and welcome comments on issues related to such impacts.

Dated: October 17, 2003.

Robert Springer,

Director, Office of Solid Waste.

[FR Doc. 03–27270 Filed 10–28–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement Nos.: 010050–012.

Title: U.S. Flag Discussion Agreement.

Parties: American President Lines, Ltd. and A.P. Moller-Maersk A/S.

Synopsis: The amendment expands the geographic scope of the agreement to include ports in Africa and Eastern Europe and updates Maersk Sealand's name.

Agreement No.: 011075–064.

Title: Central America Discussion Agreement.

Parties: APL Co. Pte Ltd.; A.P. Moller-Maersk A/S; Crowley Liner Services, Inc.; Dole Ocean Cargo Express; King Ocean Services Limited; and Seaboard Marine, Ltd.

Synopsis: The amendment adds Lykes Lines Limited, LLC as a party to the agreement.

Agreement No.: 011865.

Title: CMA–CGM/LT Amerigo Express MUS Slot Charter Agreement.

Parties: CMA CGM, S.A. and Lloyd Triestino di Navigazione S.p.A.

Synopsis: The proposed agreement would authorize CMA CGM to charter space to Lloyd Triestino in the trade between the East Coast of the United States and the western Mediterranean Sea.

Dated: October 24, 2003.

By Order of the Federal Maritime Commission

Bryant L. VanBrakle,

Secretary.

[FR Doc. 03–27278 Filed 10–28–03; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–78–03]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503, or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project: National Public Health Performance Standards Program Local Public Health Governance Performance Assessment Instrument—Revision—Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC).

CDC received approval for this data collection February 19, 2002. This request seeks approval for a revised evaluation document. The previous instrument included 23 open-ended questions. The revised instrument includes 13 questions, the majority of which are close-ended. This revised instrument will provide us better data for the purposes of analysis and elicit more valuable information for improving the instruments in the future. Additionally, the revised evaluation is similar to the evaluations included in the State Public Health System and Local Public Health System Performance Assessment Instruments (0920–0557 and 0920–0555), thus offering more opportunities for cross-analysis.

Background

Since 1998, the CDC National Public Health Performance Standards Program has convened workgroups with the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), the National Association of Local Boards of Health (NALBOH), the American Public Health Association (APHA), and the Public Health Foundation (PHF) to develop performance standards for public health systems based on the ten Essential

Services of Public Health. In the Spring of 2001, CDC conducted field tests with the local public health governance instruments in the State of Massachusetts.

CDC received approval to implement a voluntary data collection to assess the capacity of local boards of health to deliver the Essential Public Health Services. This data collection will provide a framework for local boards of health to evaluate their effectiveness. Electronic data submission will be the method of choice. If computer technology in local jurisdictions does not support electronic submission, hard copy survey instruments will be available. Local jurisdictions using hard copy survey instruments will receive assistance from State or local level field coordinators for web-based data entry.

Local boards of health will respond to the survey. An estimated 33% of approximately 3,200 United States local boards are expected to participate in the National Performance Standards Program per year. The burden hours are estimated to be 19,200.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)
Local Boards of Health Year 1	1,066	1	6
Local Boards of Health Year 2	1,067	1	6
Local Boards of Health Year 3	1,067	1	6

Dated: Friday, October 14, 2003.

Gaylon D. Morris,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention.

[FR Doc. 03–26987 Filed 10–28–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0278]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 2003 (68 FR 58974 at 59067), 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 0910–0520. The approval expires on October 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

October 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27189 Filed 10–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0486]

Determination That PIPRACIL (Piperacillin Sodium) 2-Gram, 3-Gram, and 4-Gram Vials Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PIPRACIL (piperacillin sodium) 2-gram, 3-gram, and 4-gram vials were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for piperacillin sodium 2-gram, 3-gram, and 4-gram vials.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of