Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, effective this date and pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, I hereby amend the emergency declaration to include other assistance as authorized under Title V of the Stafford Act:

Debris clearance and emergency protective measures as authorized under Title V of the Stafford Act in response to the water main break in Kent and Providence Counties (already designated for emergency provision and/or restoration of water service).

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Lacy E. Suiter,

Executive Associate Director. Response and Recovery Directorate.

[FR Doc. 96–32506 Filed 12–20–96; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) 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, N.W., Room 962. 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 No.: 202–002744–089.

Title: West Coast of South America Agreement.

Parties:

A.P. Moller-Maersk Line
Compania Chilena de Navegacion Interoceania, S.A.
Compania Sud Americana de Vapores, S.A.
Crowley American Transport, Inc.
Sea-Land Service, Inc.
South Pacific Shipping Company, Ltd. d/b/a Ecuadorian Line

Synopsis: The proposed Agreement revises Article 7(g) to file provisions pertaining to the participation of a member who has submitted its notice of resignation, and revises Article 9(d) regarding voting pursuant to polls.

Agreement No.: 202–010776–101.

Title Asia North America Rate Agreement.

Parties:

American President Lines, Ltd.
Hapag-Lloyd Aktiengesellschaft
Kawasaki Kisen Kaisha, Ltd.
A.P. Moller-Maersk Line
Mitsui O.S.K. Lines, Ltd.
Nedlloyd Lijnen B.V.
Neptune Orient Lines, Ltd.
Nippon Yusen Kaisha Line
Orient Overseas Container Line, Inc.
P&O Containers
Sea-Land Service, Inc.

Synopsis: The proposed Agreement adds a new Article 14.4 of the Agreement to provide for ''Joint Service Contracts'' with shippers upon authorizing vote of the parties. The new article also sets parameters for such contracts. The parties have requested a shortened review period.

Agreement No.: 202–011536–001.

Title: The Grand Alliance Agreement.

Parties:

Hapag-Lloyd, A.G.
Neptune Orient Lines, Ltd.
Nippon Yusen Kaisha
P&O Containers Limited

Synopsis: The parties are amending their agreement to authorize discussion and agreement, on a voluntary adherence basis, on rates, charges, classifications, rules, brokerage and forwarder compensation in the trades covered by the agreement, excluding the trade to and from the European Community.

By Order of the Federal Maritime Commission.

Dated: December 17, 1996.

Joseph C. Polking,

Secretary.

[FR Doc. 96–32475 Filed 12–20–96; 8:45 am]

BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Nominations of Topics for Evidence-based Practice Centers (EPCs)

The Agency for Health Care Policy and Research (AHCPR) invites nominations of topics for evidence reports on the prevention, diagnosis, treatment, and management of common diseases and clinical conditions and, where appropriate, the use of alternative/complementary therapies, and for technology assessments of specific medical procedures or health care technologies.

As part of the effort to reorganize and restructure its programs, AHCPR is no longer facilitating the development of clinical practice guidelines and is expanding its program of health care technology assessments. AHCPR will serve as a science partner with private-sector and other public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care delivery in the United States. The Agency's goal is to narrow the gap between what is known and what is done in health care. AHCPR will support Evidence-based Practice Centers (EPCs) to undertake scientific analyses and evidence syntheses of high-priority topics. The EPCs will produce science syntheses—evidence reports and technology assessments—that provide the scientific foundation for public and private organizations to use in developing and implementing their own practice guidelines, performance measures, and other tools to improve the quality of health care and in making decisions related to the effectiveness or appropriateness of specific health care technologies.

The process that AHCPR will employ to select priority topics for analyses by the EPCs is described below.

Background

Under Title IX of the Public Health Service Act, AHCPR is charged with enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. AHCPR accomplishes these goals through scientific research and through promotion of improvements in clinical practice (including the prevention of diseases and other health conditions) and improvements in the organization, financing, and delivery of health care services (42 U.S.C. 299–299c–6 and 1320b–12). In carrying out these purposes, AHCPR, among other activities, has in the past arranged for the development of clinical practice guidelines and has conducted assessments of health care technologies.

Through the creation of EPCs, AHCPR will be better able to serve as a science partner with private-sector and other public organizations in addressing a greater number of health care topics and a broader range of clinical conditions and health problems. The EPCs will provide a strong scientific foundation for private and public organizations to use in their own efforts to improve clinical practice. The EPCs will conduct literature reviews and assess and synthesize scientific evidence to produce evidence reports and technology assessments. The reports and assessments will provide systems of care, provider societies, health plans, public and private purchasers, States, and others a scientific foundation for development and implementation of their own practice guidelines, clinical

pathways, review criteria, performance measures, and other tools to improve the quality of care in their own settings and populations. They may also be used to inform health care decisions, such as coverage policies, based on the effectiveness or appropriateness of specific services, procedures, or technologies.

Evidence-Based Practice Centers (EPCs)

AHCPR will support the establishment of a group of EPCs. The EPCs will prepare evidence reports and technology assessments on topics for which there is significant demand by health care providers, insurers, purchasers, health-related societies, and consumer organizations. Such topics may include the prevention, diagnosis and/or treatment of particular diseases or health conditions including, where appropriate, the use of alternative/complementary therapies, as well as the appropriate use of more commonly provided services, procedures, or technologies. AHCPR will publish and widely disseminate to potential users the evidence reports and technology assessments produced by the EPCs.

Selection Criteria

Selection criteria for AHCPR evidence report and technology assessment topics include: (1) high incidence or prevalence in the general population or in major subpopulations as defined by age, gender, or ethnicity and other populations; (2) significance for the needs of the Medicare and Medicaid, and other Federal health programs; (3) high costs associated with a condition, procedure, treatment, or technology, whether due to the number of people needing care, high unit cost of care, or high indirect costs; (4) controversy or uncertainty about the effectiveness or relative effectiveness of available clinical strategies or technologies; (5) potential to inform and improve patient or provider decisionmaking; (6) potential to reduce clinically significant variations in the prevention, diagnosis, treatment, or clinical management of a disease or condition, or in the use of a procedure or technology, or in the health outcomes achieved; (7) availability of scientific data to support the study or analysis of the topic; and (8) potential opportunities for rapid implementation. The topics selected will complement AHCPR's efforts to build a balanced portfolio of evidence reports and technology assessments.

These criteria are consistent with the criteria in the Public Health Service Act; section 914 (42 U.S.C. 299b–3) for selecting priority topics for guideline development and section 904 (42 U.S.C. 299a–2) for prioritizing topics for technology assessment. The process set out in this Notice supersedes the proposed methodology for establishing priorities for health care technology assessments, that was published in the Federal Register on April 25, 1994 (59 FR 19725).

Nomination and Selection Process

All nominations of topics for AHCPR evidence reports and technology assessments should be focused on specific aspects of prevention, diagnosis, treatment and/or management of a particular condition, or on an individual procedure, treatment, or technology. Potential topics should be carefully defined and circumscribed, so that within 6 to 12 months databases can be searched, the evidence reviewed, supplemental analyses performed, and final evidence reports or technology assessments produced. Topics selected will not duplicate current and widely available clinical practice guidelines or technology assessments (unless new evidence suggests the need for revisions or updates).

Nominations should be brief (1–2 pages) and may be in the form of a letter. For each topic nominated, nominators should provide a rationale and any available supporting evidence reflecting the importance and clinical relevance of the topic. They should also indicate the potential usefulness of the evidence report or technology assessment within their professional practices or organizations. Information should include:

- A clearly defined topic, with specific questions to be answered that will establish the focus and boundaries of the report.
- Indication of the availability of data for study and if available, any information on the incidence, prevalence and/or severity of the particular disease or health condition including, if relevant, its significance for the Medicare and Medicaid populations; or the frequency of use and cost of the procedure, treatment, or technology; an indication of how the evidence report or assessment might be used within the nominator's professional or organizational setting; and any known currently available technology assessments, practice guidelines, disease management protocols, or other tools or standards pertaining to the topic and their deficiencies if any.
- References to significant differences in practice patterns and/or results, the availability of alternative therapies, and any known controversies in these areas.

Nominators of topics that are selected may have the opportunity to serve as resources to EPCs as they develop evidence reports and technology assessments. Nominators may also be requested to serve as peer reviewers of draft evidence reports and technology assessments.

AHCPR will review topic nominations and supporting information and determine final topics, seeking additional information as appropriate. Final topics will be assigned to specific EPCs.

Materials Submission and Deadline

To be considered for the first group of evidence reports and technology assessments, topic nominations should be submitted by February 21, 1997 to: Douglas B. Kamerow, M.D., M.P.H., Director, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Willco Building, Suite 310, Rockville, Maryland 20852.

Nominations may also be made electronically as an ASCII file, either as an attachment or incorporated into the body of the message, to the following e-mail address: epctopic@ahcpr.gov.

After February 21, 1997, nominations will be accepted on an ongoing basis by mail or electronically at the above addresses for topics for subsequent evidence reports and technology assessments.

All responses will be available for public inspection at the Office of the Forum for Quality and Effectiveness in Health Care, telephone (301) 594–4015, weekdays between 8:30 a.m. and 5 p.m. AHCPR will not reply to individual responses, but will consider all nominations in selecting priority topics. Topics selected will be announced from time to time in the Federal Register and in AHCPR press releases.

Request for Evidence-Based Practice Center Solicitation

To receive a copy of the contract solicitation for the EPCs, mail or telefax: requestor's name, affiliation (business or organization); address (including zip code); and telephone and telefax numbers to: Agency for Health Care Policy and Research, Office of Management, Contracts Management Staff, Attn.: Al Deal, Suite 601, 2101 East Jefferson Street, Rockville, MD 20852, telefax (301) 443–7523. The solicitation is also available as an FTP file through AHCPR's Web site: www.ahcpr.gov/news/

For Additional Information

Additional information about topic nominations can be obtained by contacting: Margaret Coopey, Health Policy Analyst, Office of the Forum for Quality and Effectiveness in Health Care, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Willco Building, Suite 310, Rockville, Maryland 20852, telephone (301) 594–4015. E-mail address mcoopey@po6.AHCPR.gov.

Dated: December 18, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96–32515 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 96N–0457]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 21, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Cosmetic Product Voluntary Reporting Program (21 CFR 720.4, 720.6, 720.8(b)) (OMB Control Number 0910–0030—Reinstatement)

Under the Federal Food, Drug, and Cosmetic Act (the act) cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) cannot legally be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has requested, under part 720 (21 CFR part 720), but does not require, that firms that manufacture, pack, or distribute cosmetics file an ingredient statement for each of their products with the agency (§ 720.4). Ingredient statements for new submissions (§ 720.1) are reported on Form FDA 2512, entitled ''Cosmetic Product Ingredient Statement'' and Form FDA 2512a, a continuation form. Changes in product formulation (§ 720.6) are also reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, FDA requests that the firm file Form FDA 2514, entitled ''Discontinuance of Commercial Distribution of Cosmetic Product Formulation'' (§ 720.6). If any of the information submitted on or with these forms is confidential, the firm may submit a request for confidentiality under § 720.8.

FDA uses the information received on these forms as input in a computer-based information storage and retrieval system. These voluntary formula filings provide FDA with the best information available about cosmetic product formulations, ingredients and their frequency of use, businesses engaged in the manufacture and distribution of cosmetics, and approximate rates of product discontinuance and formula modifications. FDA's data base also lists cosmetic products containing ingredients suspected to be carcinogenic or otherwise deleterious to humans and the public health generally. The information provided under the Cosmetic Product Voluntary Reporting Program assists FDA scientists in evaluating reports of alleged injuries and adverse reactions to the use of cosmetics. The information also is utilized in defining and planning analytical and toxicological studies pertaining to cosmetics.

FDA shares nonconfidential information from its files on cosmetics with consumers, medical professionals, and industry. For example, by submitting a Freedom of Information Act request, consumers can obtain information about which products do or do not contain a specified ingredient and about the levels at which certain ingredients are typically used. Dermatologists use FDA files to cross-reference allergens found in patch test kits with cosmetic ingredients. The Cosmetic, Toiletry, and Fragrance Association, which is conducting a review of ingredients used in cosmetics, has relied on data provided by FDA in selecting ingredients to be reviewed based on the frequency of use.

FDA estimates the burden of the cosmetic product for each submission will vary in relation to the size of the company and the breadth of its marketing activities. The estimated reporting burden of this collection of information is as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
720.1 & 720.4 (new submissions)	FDA 2512/2512a	550	4.2	2,310	0.50	1,155
720.4 & 720.6 (amendments)	FDA 2512/2512a	550	1.4	770	0.33	254
720.6 (notice of discontinuance)	FDA 2514	550	4.5	2,500	0.10	250
720.8(b) (request for confidentiality)		2	1.0	2	1.50	3
Total				5,582		1,662

There are no capital costs or operating and maintenance costs associated with this collection.