

Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224-200059.

Title: Port of Oakland Terminal Use Agreement.

Parties:

Port of Oakland (Port)  
Canadian Transport Company Limited (CTCO)

**Synopsis:** The proposed agreement provides that CTCO shall have, pursuant to the terms and conditions specified therein, the nonexclusive right to use certain assigned premises at either the Port's 7th Street Public Container Terminal or the Charles P. Howard Terminal as its published regularly scheduled Northern California port of call for its vessel operations.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

Dated: November 16, 1987.

[FR Doc. 87-26834 Filed 11-19-87; 8:45 am]

BILLING CODE 6730-01-M

### Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation Issuance of Certificate (Performance)

Notice is hereby given that the following has been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Pub. L. 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 CFR Part 540):  
Discovery Cruises, Inc./Discovery Cruises, Ltd., c/o Holland & Knight, 1200 Brickell Avenue, Miami, Florida 33131.

Date: November 17, 1987.

Joseph C. Polking,

Secretary.

[FR Doc. 87-26835 Filed 11-19-87; 8:45 am]

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### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Office of the Secretary

#### Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for

clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on October 30, 1987.

#### Health Care Financing Administration

(Call Reports Clearance Officer on 301-594-1238 for copies of package.)

1. *Hospital and Hospital Health Care Complex Cost Report*—0938-0050—This form is used by hospitals and hospital health care complexes to report their health care costs and by their servicing fiscal intermediaries to determine amounts reimbursable for the services furnished Medicare beneficiaries. Respondents: Businesses or other for-profit. Number of Respondents: 7,000; Frequency of Response: Annually; Estimated Annual Burden: 4,433,560 hours.

2. *Medicare Common Claims Form*—0938-0008—Claims for reimbursement can be acted on in a timely and accurate manner when forms are used to file Part B medical and other health services provided by physicians/suppliers. Respondents: Individuals or households. Number of Respondents: 326,110,000; Frequency of Response: Occasionally; Estimated Annual Burden: 58,623,707 hours.

3. *Information Collection Requirements in the Hospice Case Regulation*—0938-0302—These information collections are needed to implement the Medicare hospice benefit. Respondents: Individuals or households, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations. Number of Respondents: 400; Frequency of Response: Annually; Estimated Annual Burden: 466,300 hours.

4. *Laboratory Personnel Qualification Appraisal*—0938-0049—This form must be completed by personnel employed by independent laboratories certified by Medicare. It is submitted to the State agency surveyor which verifies that the laboratories' personnel meet Federal regulatory standards. Respondents: Businesses or other for-profit. Number of Respondents: 3,000; Frequency of Response: Occasionally; Estimated Annual Burden: 1,000 hours.

OMB Desk Officer: Allison Herron.

#### Public Health Services

(Call Reports Clearance Officer on 202-245-2100 for copies of package.)

#### Food and Drug Administration

1. *Protection of Human Subjects*—Recordkeeping and reporting requirements for Institutional Review Boards (21 CFR Part 56)—0910-0130—Documentation of the Institution Review

Board activities and retention of those records is necessary for FDA to be able to assess compliance with regulations during inspections. Respondents: Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations. Number of Respondents: 3,000; Frequency of Response: Occasionally; Estimated Annual Burden: 23,400 hours.

2. *Laxative Drug Products for OTC Human Use*—0910-0207—This proposed rule establishes conditions for the marketing of laxative drug products classified safe and effective for OTC use. One provision of the proposed rule is preparation and distribution of directions related to the use of bowel cleansing systems in evacuating the bowel prior to surgery or x-ray. Respondents: Businesses or other for-profit. Number of Respondents: N/A; Frequency of Response: Occasionally; Estimated Annual Burden: N/A.

3. *Medical Device and Laboratory Product Problem Reporting Program (PRP)*—0910-0143—This program provides information needed to monitor the safety and effectiveness of medical devices and radiological products regulated by Center for Devices Radiological Health. Respondents: Individuals or households, State or local governments, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions. Number of Respondents: 2,300; Frequency of Response: Occasionally; Estimated Annual Burden: 575 hours.

OMB Desk Officer: Shanna Koss.

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

HCFA: 301-594-1238

PHS: 202-245-2100

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503.

ATTN: (name of OMB Desk Officer).

Dated: November 16, 1987.

James F. Trickett,

Deputy Assistant Secretary, Administrative and Management Services.

[FR Doc. 87-26800 Filed 11-19-87; 8:45 am]

BILLING CODE 4150-04-M

## Centers for Disease Control

## Requirement of Certification of Used Tire Casings From Asia Prior to Entry Into the United States

**AGENCY:** Centers for Disease Control (CDC), Public Health Service, HHS.

**ACTION:** Notice of requirement of certification of used tire casings from Asia prior to entry into the United States.

**SUMMARY:** It has been demonstrated that the Asian tiger mosquito is being imported into the United States in used tire casing. Consequently, the Public Health Service is taking action to prevent the further importation.

**Background:** In August 1985, the Asian tiger mosquito (*Aedes albopictus*) was found to have infested one county in Texas. This mosquito can transmit a number of viral diseases to humans, and its presence is considered to constitute a significant public health threat. In 1986, *Aedes albopictus* was found to have spread to other locations in the United States and by October 1, 1987, 15 States had been found to be infested. Field evaluations in the spring and early summer of 1987 have demonstrated that this species successfully survives temperate winters as far north as Indiana.

Surveys conducted by the Centers for Disease Control (CDC) have established that *Aedes albopictus* and other mosquito species are being imported into the United States from Asia in used tire casings.

**Implementation Procedures:** To prevent the further importation of this mosquito and the possible introduction, transmission, or spread of communicable diseases (in these mosquitoes), CDC is taking the following action: Under the authority of section 361 of the Public Health Service Act and 42 CFR 71.32(c), CDC will require that all used tire casing originating from Japan, Korea, Taiwan, Hong Kong, Thailand, and elsewhere in Asia be certified as being dry, clean, and disinfected.

Disinsection and certification should be accomplished by the exporter using one of the following methods:

A. Tire casing must be clean and free from water and fumigated, according to label instruction, with at least 2 pounds of methyl bromide fumigant per 1,000 feet<sup>3</sup> for 24 hours.

b. Tire casing must be clean and free from water and subjected to dry heat at a temperature of 120°F (49°C) for >30 minutes.

C. Tire casing must be clean and free from water and subjected to steam or a

pressurized spray of hot water (190°F; 88°C) containing detergent.

After tires have been disinfected they must be kept dry.

The exporter must sign the certificate specifying the method of disinsection used and the date the tires were treated. The importer or his/her agent will sign the certificate at the time of clearance by the U.S. Customs Service and the importer or his/her agent will mail the original copy of the certificate to the Centers for Disease Control, Division of Quarantine, Atlanta, Georgia 30333.

The Customs Service will ensure that all shipments of used tire casings from Asia are accompanied by a valid CDC Disinsection Certificate before releasing the cargo. Shipments of tires that do not have proper documentation will be kept separated from other cargo pending appropriate disposition. All costs incurred for final disposition (including disinsection at a U.S. port of entry) will be borne by the importer.

CDC will make site visits to the major exporting countries to verify disinsection capabilities, will perform periodic inspections of shipments of used tire casings to monitor compliance, and will receive copies of the disinsection certificates from the U.S. Customs Service.

**Effective Date:** January 1, 1988.

**For Further Information, Copies of Technical Specifications, or Certification Forms Please Contact:** Mr. Tony D. Perez (404-329-2574), Centers for Disease Control, Division of Quarantine, Atlanta, Georgia 30333.

**Dated:** November 16, 1987.

**Glenda S. Cowart,**  
*Director, Office of Program Support, Centers for Disease Control.*

[FR Doc. 87-26792 Filed 11-19-87; 8:45 am]

BILLING CODE 4160-18-M

## Food and Drug Administration

[Docket No. 82F-0334]

Air Products and Chemicals, Inc.;  
Withdrawal of Food Additive Petition

**AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice to future filing of a petition proposing that the food additive regulations be amended to provide for the safe use of 2,4,7,9-tetramethyl-5-decyn-4,7-diol as a component of coatings for paper and paperboard in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Edward J. Machuga, Center for Food

Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of December 3, 1982 (47 FR 54547), FDA published a notice that it had filed a petition (FAP 2B3657) from Air Products and Chemicals, Inc., Box 538, Allentown, PA 18105, proposing that 21 CFR 176.170 be amended to provide for the safe use of 2,4,7,9-tetramethyl-5-decyn-4,7-diol as a component of coatings for paper and paperboard in contact with food. Air Products and Chemicals, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

**Dated:** November 12, 1987.

**Fred R. Shank,**  
*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 87-26781 Filed 11-19-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87F-0344]

Filing of Food Additive Petition;  
NutraSweet Co.

**AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the NutraSweet Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in baked goods and baking mixes.

**FOR FURTHER INFORMATION CONTACT:** Joseph Leginus, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7A4044) has been filed by the NutraSweet Co., 4711 Golf Rd., Skokie, IL 60076, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the use of aspartame as a sweetener in baked goods and baking mixes, where standards of identity do not preclude its use.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be

published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 12, 1987

Fred R. Shank,

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 87-26780 Filed 11-19-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87N-0381]

### Drug Export; Methotrexate Sodium Tablets

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Lederle Laboratories has filed an application requesting approval for the export of the human drug Methotrexate Sodium Tablets to the United Kingdom.

**ADDRESS:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Rudolf Apodaca, Center for Drugs and Biologics (HFN-310), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8063.

**SUPPLEMENTARY INFORMATION:** The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Lederle Laboratories, Pearl River, New York 10965, has filed an application requesting approval for the export of the drug Methotrexate Sodium Tablets to

the United Kingdom. This drug is used in the treatment of neoplastic disease and severe cases of uncontrolled psoriasis unresponsive to conventional therapy. The application was received and filed in the Center for Drugs and Biologics on September 29, 1987, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by November 30, 1987, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802, Pub. L. 99-660 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drugs and Biologics (21 CFR 5.44).

Dated: November 4, 1987.

Daniel L. Michels,

*Director, Office of Compliance, Center for Drugs and Biologics.*

[FR Doc. 87-26779 Filed 11-19-87; 8:45 am]

BILLING CODE 4160-01-M

### Health Care Financing Administration

#### Statement of Organization, Functions, and Delegations of Authority

Part F. of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA) (**Federal Register**, Vol. 51, No. 201, pp. 37076-37077, dated Friday October 17, 1986) is amended to reflect a change in the organizational structure of the Office of Operations Support (OOS), Office of Research and Demonstrations (ORD), Associate Administrator for Program Development. OOS is being reorganized to consolidate all administrative management functions within ORD in one component.

The specific changes to Part F are as follows:

- Section FQ.20.B.3., is deleted in its

entirety and replaced by a new functional statement that reads as follows:

#### 3. Office of Operations Support (FQBC).

Provides policy direction, coordination, and control to the Office of Research and Demonstrations in the areas of budget, financial and accounting operations, personnel, workplanning, management evaluation and analysis, and administrative services. Directs the research and demonstration project grant, cooperative agreement and procurement programs. Directs and plans ongoing research publications and information resources programs. Participates with departmental components in a wide range of experimental health care delivery projects. Performs claims adjudication, reimbursement, and data collection for demonstration projects. Provides a setting for testing proposed policies and procedures which impact on fiscal intermediary operations and provides the capacity for serving specialized providers. Directs ORD's correspondence and tracking and control system. Coordinates the development of, and responses to, regulations related to ORD. Responsible for ORD's Freedom of Information requests.

• Section FQ.20.B.3.a, Division of Executive Operations (FQBC1), is deleted in its entirety and replaced by the following:

#### a. Division of Program Support (FQBC3)

Plans, organizes, and administers the extramural ORD research and demonstration (grants, cooperative agreements, and contracts) program assuring that both technical and administrative requirements are met. Plans and directs an ongoing publications dissemination and information resources program. Provides assistance in the coordination and production of major written documents, plans, and reports.

Date: October 20, 1987.

William L. Roper,

*Administrator, Health Care Financing Administration.*

[FR Doc. 87-26840 Filed 11-19-87; 8:45 am]

BILLING CODE 4120-01-M