

Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of Title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202-011432-003.

Title: Pacific Latin America

Agreement.

Parties:

Sea-Land Service, Inc.

Central American Container Line, S.A.

A.P. Moller-Maersk Line

Synopsis: The proposed amendment deletes Central America Container Line, S.A., changes the notification period for independent action from two days to five days and authorizes the Conference Chairman or his designee to sign and file any amendments to the basic Agreement.

Dated: February 13, 1995.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 95-3981 Filed 2-16-95; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL MARITIME COMMISSION

[Docket No. 95-03]

Puerto Rico Freight Systems, Inc. v. R & S Trading and J.C. Trading; Notice of Filing of Complaint and Assignment

Notice is given that a complaint filed by Puerto Rico Freight Systems, Inc. ("Complainant") against R & S Trading and J.C. Trading ("Respondents") was served February 14, 1995. Complainant alleges that Respondents have violated sections 3, 14, 15, 16, 17, and 18 of the Shipping Act of 1916, 46 U.S.C. app. 804, 812, 814, 815, 816 and 817(b)(1), by issuing false manifests, shipping materials in containers which are not manifested or declared by Respondents, operating without a tariff, waiving fees for ocean freight, competing with other freight operators who adhere to a tariff to their disadvantage, and operating without bills of lading.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61,

and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by February 14, 1996, and the final decision of the Commission shall be issued by June 14, 1996.

Joseph C. Polking,

Secretary.

[FR Doc. 95-4027 Filed 2-16-95; 8:45 am]

BILLING CODE 6730-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Committee on Vital and Health Statistics: Meeting

Pursuant to Pub. L. 92-463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Times and Dates: 1 p.m.-5 p.m., March 8, 1995; 9 a.m.-5 p.m., March 9, 1995; 9 a.m.-3 p.m., March 10, 1995.

Place: Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201.

Status: Open.

Purpose: The purpose of this meeting is for the committee to consider reports from each NCVHS subcommittee; to receive reports from offices of the Department of Health and Human Services; to explore information needs for health reform; and to address new business as appropriate.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436-7050.

Dated: February 13, 1995.

William H. Gimson,

Acting Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-3999 Filed 2-16-95; 8:45 am]

BILLING CODE 4163-18-M

Food and Drug Administration

[Docket No. 95M-0023]

Molecular Biosystems, Inc.; Premarket Approval of Alunex®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Molecular Biosystems, Inc., San Diego, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Alunex®. After reviewing the recommendation of the Radiological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 5, 1994, of the approval of the application.

DATES: Petitions for administrative review by March 20, 1995.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212.

SUPPLEMENTARY INFORMATION: On February 5, 1991, Molecular Biosystems, Inc., San Diego, CA 92121, submitted to CDRH an application for premarket approval of Alunex®. The device, which is a suspension of air-filled microspheres made from sonicated 5 percent human albumin, is an ultrasound contrast media that is used as an aid for ultrasound contrast enhancement of ventricular chambers and improvement of endocardial border definition in patients with suboptimal echoes undergoing ventricular function and regional wall motion studies.

On July 29, 1992, the Radiological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August

5, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before March 20, 1995, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: February 7, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95-4057 Filed 2-16-95; 8:45 am]

BILLING CODE 4160-01-F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Radiological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. March 6, 1995, 8 a.m., Corporate Bldg., conference room 20G, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 and reference the FDA panel meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9

a.m. to 4 p.m.; Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Radiological Devices Panel, code 12526. If anyone who is planning to attend the meeting will need any special assistance as defined under the Americans with Disabilities Act, please communicate with the contact person.

General function of the committee.

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 1, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss clinical data requirements (experimental designs, protocols, quality assurance, etc.) for digital mammography submissions. Copies of a draft protocol are available from the contact person.

Blood Products Advisory Committee

Date, time, and place. March 23 and 24, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person.

Open committee discussion, March 23, 1995, 8 a.m. to 9:30 a.m.; open public hearing, 9:30 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:30 p.m.; open committee discussion, March 24, 1995, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 5:30 p.m.; Linda A. Smallwood, Center for Biologics