Draft restrictions at three of the marinas would exclude a certain number of the larger vessels from accessing the pumpouts at these three marinas. Montauk Sportsman's Dock has a water depth of 6 feet; it is estimated that 5% of the vessels would be excluded. Captain's Cove Marina has a water depth of 5 feet; it is estimated that 10% of the vessels would be excluded. Gone Fishing Marina has a water depth of 6 feet; it is estimated that 5% of the vessels would be excluded. For these excluded vessels, there are seven other pumpouts and three pumpout boats available for their use.

Vessel waste generated from the pump-out facilities operated by the Town of East Hampton is conveyed to a storage tank at the municipal scavenger waste treatment plant. The waste is hauled from the scavenger plant to the Bergen Point Wastewater Treatment Plant. With two exceptions, the other marinas empty their pumpouts into large storage tanks ranging in size from 500 gallons to 2,376 gallons. A certified hauler collects, transports and disposes of the sewage in accordance with all Federal, State and local laws. The two exceptions are Harbor Marina, which uses an on-site Bio-Robi septic system, and Captain's Cove Marina, which does not have a pumpout facility and instead uses a certified waste hauler to pumpout a vessel on request.

According to the petition, the slip and mooring capacity for each harbor or creek is as follows:

Name of harbor or creek	Number of slips/ moorings/docks
Northwest Creek	21
Three Mile Harbor	1067
Accabonac Harbor	56
Hog Creek	195
Napeague Harbor	20
Lake Montauk	1274
Total	2577

The New York State Department of State conducted a survey of recreational vessels using aerial photography during August 1995 for the New York State Clean Vessel Act Plan. Analysis of the photographs provided information on the total numbers of vessels by water body. Data indicates the following peak season vessel population in the proposed NDAs in East Hampton:

Name of harbor or creek	Number of vessels
Northwest Creek	No data available
Three Mile Harbor	734
Accabonac Harbor	38
Hog Creek	No data available
Napeague Harbor	56
Lake Montauk	883
Total	1711

Information regarding vessel population based on length shows that 63% of the boats are less than 40 feet and 37% of the vessels are 40 feet or greater in length. These percentages are based on a survey of overnight and long term occupancy and omitted marinas with recreational small crafts. Based on the number and size of boats, and using various methods to estimate the number of holding tanks, it is estimated that 5 to 8 pumpouts are needed to service the vessel population in the proposed NDAs. Currently, ten pumpouts and three pumpout boats exist in the proposed NDAs.

The EPA hereby makes a *tentative affirmative determination* that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for Northwest Creek, Three Mile Harbor, Hog Creek, Accabonac Harbor, Napeague Harbor and Lake Montauk in the Town of East Hampton, New York. A final determination on this matter will be made following the 30 day period for public comment. A final affirmative determination would result in a New York State prohibition of any sewage discharges from vessels in Northwest Creek, Three Mile Harbor, Hog Creek, Accabonac Harbor, Napeague Harbor and Lake Montauk.

Comments and views regarding this petition and EPA's tentative determination may be filed on or before December 7, 1998. Comments or requests for information or copies of the applicant's petition should be addressed to Walter E. Andrews, U.S. Environmental Protection Agency, Region II, Water Programs Branch, 290 Broadway, 24th Floor, New York, New York, 10007–1866. Telephone: (212) 637–3880.

Dated: October 21, 1998.

Jeanne Fox,

Regional Administrator, Region II.

[FR Doc. 98–29660 Filed 11–4–98; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Request for Additional Information

Agreement No.: 203–011474–002.

Title: The CSAV/CCNI Car Carrier Agreement.

Parties: Compania Sud Americana de Vapores S.A. Compania Chileana de Navegacion Interoceanica S.A.

Synopsis: The Federal Maritime Commission hereby gives notice, pursuant to section 6(d) of the Shipping Act of 1984, 46 U.S.C. app. §§ 1701 *et seq.*, that it has requested the agreement parties to submit additional information regarding their agreement. Further information is necessary so the Commission can determine the impact of the proposed agreement modification. This action prevents the agreement from becoming effective as originally scheduled.

By Order of the Federal Maritime Commission.

Dated: October 30, 1998.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 98–29596 Filed 11–4–98; 8:45 am]

BILLING CODE 6730–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee, NCEH Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Advisory Committee to the Director, National Center for Environmental Health.

Times and Dates: 10 a.m.–5:15 p.m., November 23, 1998; 8:30 a.m.–3:30 p.m., November 24, 1998.

Place: CDC National Center for Environmental Health, Building 102, Room 2201A/B, 4770 Buford Highway N.E., Chamblee, Georgia, telephone 770/488–7020.

Status: Open to the public, limited only by space available. The meeting room will accommodate approximately 19 Committee members and presenters, plus 20 observers.

Matters To Be Discussed: The Committee will provide advice on environmental public health problems that potentially pose the greatest risks to human health and may not be receiving adequate attention; the primary prevention of birth defects and developmental and other disabilities; the prevention of secondary conditions in persons with a primary disability; and the research agenda needed to improve the science base relative to human health effects and environmental exposures and that will ultimately provide sound human health data for policy and decision-making. The Committee will also review NCEH's 1998–2002 Strategic Plan.

Persons wishing to make written or oral comments at the meeting should notify the contact person in writing or by telephone no later than close of business November 18, 1998.

Requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit the time of each presenter.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Anne Wilson, Program Analyst, Office of the Director, NCEH, CDC, 4770 Buford Highway, NE, M/S F49, Atlanta, Georgia 30341–3724, telephone 770/488–7321, e-mail amw6@cdc.gov.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 30, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–29601 Filed 11–4–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 1, 1998, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Rhonda W. Stover or Sandra L. Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will jointly discuss new drug application (NDA) N20–629, to switch penciclovir (Denavir®, SmithKline Beecham) topical cream from prescription status to over-the-counter status for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 24, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 24, 1998, 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 requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 27, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–29561 Filed 11–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0298]

Guidance for Industry on General/ Specific Intended Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry on General/ Specific Intended Use.'' FDA developed this guidance to satisfy a new section of the Federal Food, Drug, and Cosmetic Act (the act), which was added by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This new section directs the agency to issue guidance explaining the general principles used by FDA in determining when a specific use may be added to a legally marketed device using premarket notification (510(k)) procedures and when a specific use triggers the need for a premarket approval (PMA) application.

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your electronic or written request, or fax your request to 301–443–8818. Submit written comments on ''Guidance for Industry on General/Specific Intended Use'' to the contact person. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance entitled ''Guidance for Industry on General/Specific Intended Use.''

FOR FURTHER INFORMATION CONTACT: Daniel G. Schultz, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–5072.

SUPPLEMENTARY INFORMATION:

I. Background

Congress indicated that FDA should provide additional guidance on the approach that the agency takes when evaluating whether a new use, which appears to fall within the scope of the intended use of a legally marketed predicate device, is a new intended use that would require a PMA. This guidance is issued in accordance with the new section 513(i)(1)(F) of the act (21 U.S.C. 360c(i)(1)(f)), which was added by section 206 of FDAMA. The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA application. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is the device with a new, specific indication for use likely to be found to be substantially equivalent to a device legally marketed for a general indications for use? Conversely, when does a specific indication for use become a new intended use that requires submission of a PMA to establish the safety and effectiveness of the device? FDA announced the