*Title:* HMM/Hanjin Reciprocal Space Charter Agreement.

*Parties:* Hyundai Merchant Marine Co., Ltd. and Hanjin Shipping Co., Ltd.

*Filing Parties:* Robert B. Yoshitomi, Esq., Nixon Peabody LLP, 555 West 5th Street, 46th Floor, Los Angeles, CA 90013–1025 and David F. Smith, Esq., Sher & Blackwell LLP, 1850 M Street, NW., Suite 900, Washington, DC 20036.

*Synopsis:* The agreement authorizes the parties to share vessel space in the trade between U.S. East Coast ports, on the one hand, and ports in the Indian Subcontinent, Middle East, and Asia, on the other. The parties requested expedited review.

By Order of the Federal Maritime Commission.

Dated: September 3, 2009.

**Karen V. Gregory,**

*Secretary.*

[FR Doc. E9–22055 Filed 9–11–09; 8:45 am]

**BILLING CODE 6730–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0395]**

### Draft Guidance for Industry and Food and Drug Administration Staff; Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation.'' This draft guidance provides FDA's proposed recommendations on clinical trial designs for surgical ablation devices intended for the treatment of atrial fibrillation. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 14, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled ''Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elias Mallis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1312, Silver Spring, MD 20993, 301–796–6216.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Atrial fibrillation (AF) is a complex arrhythmia of the heart. Its precise mechanisms remain unclear. This draft guidance describes elements of suggested clinical study design for surgical ablation devices used to treat patients with longstanding persistent AF and patients with symptomatic paroxysmal AF, such as inclusion and exclusion criteria and assessment of effectiveness, which may differ for these patient populations.

#### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on clinical study designs for surgical ablation devices for treatment of atrial fibrillation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

#### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1676 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

#### IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR 50 and 21 CFR 56 have been approved under OMB control number 0910–0130; and the collections of information under 21 CFR part 814 have been approved under OMB control number 0910–0231.

#### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 28, 2009.

**Catherine M. Cook,**

*Associate Director for Regulations and Policy, Center for Devices and Radiological Health.*

[FR Doc. E9–22019 Filed 9–11–09; 8:45 am]

**BILLING CODE 4160–01–S**