ITEMS TO BE DISCUSSED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personal decisions, or internal rules and practices. Matters concerning participation in civil actions or proceedings or arbitration. Information the premature disclosure of which would be likely to have a Considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary.

[FR Doc. 2016–27328 Filed 11–8–16; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010099–064.

Title: International Council of Containership Operators.

Parties: Maersk Line A/S; CMA CGM, S.A.; China COSCO Shipping Corporation Limited; Crowley Maritime Corp.; Evergreen Marine Corporation (Taiwan), Ltd.; Hamburg-Süd KG; Hapag-Lloyd AG and Hapag-Lloyd USA LLC; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; MSC Mediterranean Shipping Company S.A.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line, Ltd.; Pacific International Lines (Pte) Ltd.; United Arab Shipping Company (S.A.G.); Wan Hai Lines Ltd.; Yang Ming Transport Marine Corp.; and Zim Integrated Shipping Services Ltd.

Filing Party: John Longstreth, Esq.; K & L Gates LLP; 1601 K Street NW., Washington, DC 20006–1600.

Synopsis: The amendment deletes Hanjin Shipping Co., Ltd. as a party to the Agreement.

Agreement No.: 012129–002.

Title: EUKOR/''K'' Line Space Charter Agreement.

Parties: EUKOR Car Carriers, Inc. and Kawasaki Kisen Kaisha, Ltd.

Filing Party: John P. Meade, Esq.; Vice-President; K- Line America, Inc.; 6009 Bethlehem Road; Preston, MD 21655.

Synopsis: The amendment adds the Dominican Republic, Grand Cayman, St. Maarten, Haiti, and the Bahamas to the geographic scope of the Agreement.

Agreement No.: 012395–001.

Title: MSC/ACL Trans-Atlantic Space Charter.

Parties: Atlantic Container Line A.B. and MSC Mediterranean Shipping Company S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor LLP; 1200 Nineteenth St. NW., Washington, DC 20036.

Synopsis: The amendment extends the duration of the Agreement for one year.

Agreement No.: 012439.

Title: THE Alliance Agreement.

Parties: Hapag-Lloyd AG and Hapag-Lloyd USA LLC (acting as one party); Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; and Yang Ming Marine Transport Corp.

Filing Party: David F. Smith, Esq.; Cozen O'Conner; 1200 Nineteenth Street NW., Washington, DC 20036.

Synopsis: The Agreement authorizes the Parties to charter and exchange space on one another's vessels and to rationalize, coordinate and cooperate with respect to the Parties' transportation services and operations.

By Order of the Federal Maritime Commission.

Dated: November 7, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–27185 Filed 11–9–16; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3275]

Product Labeling for Certain Ultrasonic Surgical Aspirator Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices.'' FDA is providing a specific labeling recommendation in this guidance to promote the safe and effective use of ultrasonic surgical aspirator devices. The labeling recommendation is being made in light of the risk of tissue dissemination and relates to use of these devices in the removal of uterine fibroid. 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 of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 9, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted,

marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–3275 for ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1524, Silver Spring, MD 20993–0002, 301–796–6424.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing a draft guidance to recommend the addition of a specific safety statement to the product labeling of certain ultrasonic surgical aspirator devices. This draft guidance applies to ultrasonic surgical aspirator devices intended for use in general surgery, laparoscopy, and/or gynecologic surgery. Ultrasonic surgical aspirator devices are surgical tools intended to fragment, emulsify, and aspirate hard and soft tissue. However, the mechanism of action of ultrasonic surgical aspirator devices creates the potential for tissue dissemination. In light of this risk, FDA is providing a specific labeling recommendation in this draft guidance regarding use of these devices in the removal of uterine fibroids.

FDA is aware that ultrasonic surgical aspirator devices are sometimes used to treat advanced malignancy through cytoreduction (also known as debulking). When used in advanced cancers, the risk of adverse clinical effects from tissue dissemination may be small compared to the device's potential benefits.

In certain clinical circumstances, however, the unintended dissemination of cancerous cells may have a significant adverse effect that outweighs any demonstrated benefits. Specifically, use of an ultrasonic surgical aspirator device during treatment for symptomatic uterine fibroids on a woman with an occult uterine sarcoma could result in dissemination of this cancer. Therefore, FDA recommends that manufacturers of ultrasonic surgical aspirator devices with a general indication for use in general surgery, laparoscopy, and/or gynecologic surgery prominently include a specific contraindication in their product labeling that the device is not indicated for and should not be used for the removal of uterine fibroids.

FDA is seeking comment on specifically how these devices are used in practice and whether the proposed contraindication appropriately limits the patient population when considering the clinical utility of ultrasonic surgical aspirator devices.

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 current thinking of FDA on Product Labeling for Certain Ultrasonic Surgical Aspirator Devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Product Labeling for Certain Ultrasonic Surgical Aspirator Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500072 to identify the guidance you are requesting.

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 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: November 4, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27106 Filed 11–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit either electronic or written comments on the collection of information by January 9, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0618 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,