Type of Review: Extension of a currently approved collection.

Respondents: Not-for-profit institutions; State, local or Tribal governments.

Number of Respondents and Responses: 21,019 respondents with multiple responses; 27,737 responses.

Estimated Time per Response: .0025–12 hours.

Frequency of Response: Recordkeeping requirement; On occasion reporting requirement; Monthly reporting requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in sections 154(i), 303, 308 and 325(a) of the Communications Act of 1934, as amended.

Total Annual Burden: 35,371 hours.

Total Annual Costs: $39,750.

Privacy Act Impact Assessment: This information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

Nature and Extent of Confidentiality: There is no need for confidentiality with this information collection.

Needs and Uses: This submission is being made as an extension to an existing information collection pursuant to 44 U.S.C. 3507. This submission covers FCC Form 318 and its accompanying instructions and worksheets. FCC Form 318 is required: (1) To apply for a construction permit for a new Low Power FM (LPFM) station; (2) to make changes in the existing facilities of such a station; (3) to amend a pending FCC Form 318 application; or (4) to propose mandatory time-sharing.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–04567 Filed 3–12–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, March 19, 2019 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personnel decisions, or internal rules and practices.

Investigatory records compiled for law enforcement purposes and production would disclose investigative techniques.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

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

Laura E. Sinram,

Deputy Secretary of the Commission.

[FR Doc. 2019–04666 Filed 3–11–19; 11:15 am]

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 by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201229–002.

Agreement Name: Marine Terminal Services Agreement Port of Houston Authority and Maersk Line A/S.

Parties: Port of Houston Authority and Maersk Line A/S.

Filing Party: Chasless Yancy; Port of Houston Authority.

Synopsis: The amendment revises the Consumer Price Index adjustment month for the MTSA from October to July.

Proposed Effective Date: 3/6/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/2076.

Agreement No.: 012212–004.

Agreement Name: NYK/Grimaldi Cooperative Working Agreement.

Parties: Nippon Yusek Kaisha; and Grimaldi Deep Sea S.P.A. and Grimaldi Euromed S.P.A. (acting as a single party).

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The amendment converts the Agreement from a one-way space charter to a reciprocal space charter arrangement.

Proposed Effective Date: 3/6/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/262.

Agreement No.: 201291.

Agreement Name: Turkon/Hapag-Lloyd Space Charter and Sailing Agreement.

Parties: Hapag-Lloyd AG and Turkon Konteyner Tasimacilik ve Denizcilik A.S.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: The Agreement authorizes the parties to operate a service between the U.S. Atlantic Coast and ports in Spain, Turkey, and Egypt. The parties request expedited review.

Proposed Effective Date: 4/21/2019.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/21339.

Dated: March 8, 2019,

Rachel Dickon,

Secretary.

[FR Doc. 2019–04637 Filed 3–12–19; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0358]

Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of drugs or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations on the inclusion of pediatric patients (*i.e.,* children and adolescents) in clinical trials for cancer treatments. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the

agent in clinical practice without jeopardizing patient safety.

DATES: Submit either electronic or written comments on the draft guidance by May 13, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–0358 for ''Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients.'' This draft guidance provides recommendations on the inclusion of pediatric patients in clinical trials of drugs or biological products regulated by CDER and CBER for the treatment of cancer.

A clinical trial's eligibility criteria are essential components of the trial, defining the characteristics of the study population. Eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. However, some eligibility criteria have become commonly accepted over time or used as a template across trials without clear scientific or clinical rationale. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. Broadening cancer trial eligibility criteria can maximize the generalizability of trial results and the ability to understand the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice without jeopardizing patient safety. Early evaluation and development of potentially effective drugs, particularly targeted drugs, in pediatric patients may provide information on safe and effective use, reduce risks associated with off label use, and accelerate the development of effective, innovative therapies for pediatric patients.

The guidance includes recommendations regarding minimum

age eligibility criteria and addresses specific situations in which the inclusion of children (for the purposes of this guidance, ages 2 years to younger than 12 years) and adolescents (for the purposes of this guidance, ages 12 years to 17 years) is appropriate in cancer trials (*i.e.,* based on disease biology and clinical course, molecular target of the investigational drug, and/or its molecular mechanism). In addition, the guidance includes ethical and regulatory considerations for including pediatric patients.

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 ''Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients.'' 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. This guidance is not subject to Executive Order 12866.

II. 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 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov*.

Dated: March 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04585 Filed 3–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1540]

Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials; Guidance for Industry; 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 a final guidance for industry entitled ''Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials.'' The purpose of this guidance is to provide the pharmaceutical industry, clinical investigators, and institutional review boards with information to facilitate the inclusion of adolescent patients (for purposes of this guidance, defined as ages 12 to 17) in relevant adult oncology clinical trials. The guidance focuses on appropriate patient selection criteria for the inclusion of adolescent patients in adult oncology clinical trials at various stages of drug development, considerations for dosing and pharmacokinetic evaluations, safety monitoring, and ethical considerations.

DATES: The announcement of the guidance is published in the **Federal Register** on March 13, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1540 for ''Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/*