random audits. The random audits are conducted on the carriers that use numbering resources in order to verify the accuracy of numbering data reported on FCC Form 502, and to monitor compliance with FCC rules, orders and applicable industry guidelines. Failure of the audited carriers to respond to the audits can result in penalties. Based on the final audit report, evidence of potential violations may result in enforcement action.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2020–04967 Filed 3–10–20; 8:45 am]

BILLING CODE 6712–01–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, relevant information, or documents regarding the agreements to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573. Comments will be most helpful to the Commission if received within 12 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.: 201334.

Agreement Name: COSCO/ONE/OOCL/YM EMED–USEC Vessel Sharing Agreement.

Parties: COSCO SHIPPING Lines Co., Ltd.; Ocean Network Express Pte. Ltd.; Orient Overseas Container Line Limited; and Yang Ming Marine Transport Corp., Yang Ming (UK) Ltd., and Yang Ming (Singapore) Pte. Ltd. (acting as a single party).

Filing Party: Joshua Stein; Cozen O'Connor.

Synopsis: The Agreement authorizes the parties to cooperate on the provision of a service operating between the U.S. East Coast and ports in the Mediterranean.

Proposed Effective Date: 3/4/2020.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/27479.

Agreement No.: 012056–002.

Agreement Name: WWOcean/EUKOR Joint Operating Agreement.

Parties: Wallenius Wilhelmsen Ocean AS and EUKOR Car Carriers, Inc.

Filing Party: Wayne Rohde; Cozen O'Connor.

Synopsis: This amendment revises Article 5.6(c) of the Agreement to exclude tug services from the services for which the parties are authorized to negotiate jointly.

Proposed Effective Date: 3/5/2020.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/2021.

Dated: March 6, 2020.

Rachel Dickon,

Secretary.

[FR Doc. 2020–05002 Filed 3–10–20; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0420]

Providing Regulatory Submissions in Alternate Electronic Format; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Alternate Electronic Format.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), Congress granted FDA the authority to implement the statutory electronic submission requirements in guidance. In response, FDA implemented binding guidance requiring that new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain drug master files (DMFs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) be submitted to the Agency in electronic common technical document (eCTD) format. Recognizing that some submissions are exempt from this requirement and that waivers of the requirement may be granted on a case-by-case basis, the Agency is issuing this draft guidance to describe the alternate electronic format sponsors or applicants should use for submissions covered under such exemptions and waivers.

DATES: Submit either electronic or written comments on the draft guidance by May 11, 2020 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–2020–D–0420 for ''Providing Regulatory Submissions in Alternate Electronic Format.'' 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.govinfo.gov/content/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 Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926; or 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Alternate Electronic Format.'' This draft guidance provides recommendations on an alternate electronic format for submissions that are covered under an exemption from or granted a waiver of the requirements of section 745A(a) of the FD&C Act (21 U.S.C. 379k–1). These recommendations pertain to the electronic format of content in NDAs, ANDAs, DMFs, certain BLAs, and certain INDs submitted to the Center for Drug Evaluation and Research or to the Center for Biologics Evaluation and Research.

This draft guidance includes information on: (1) How to submit in alternate electronic format (without xml backbone), (2) submission of FDA forms, (3) pre-submission considerations, (4) submission structure, (5) file formats and versions, (6) datasets and study information, (7) transmitting electronic submissions, and (8) receipt dates.

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 ''Providing Regulatory Submissions in Alternate Electronic Format.'' 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.

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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, or *https://www.regulations.gov.*

Dated: March 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04994 Filed 3–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

Q3D(R1) Elemental Impurities; International Council for Harmonisation; 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 revised final guidance for industry entitled ''Q3D(R1) Elemental Impurities.'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This guidance finalizes the draft guidance ''Q3D(R1) Elemental Impurities'' published on July 13, 2018. This guidance revises the existing guidance for industry ''Q3D Elemental Impurities'' and provides an updated permitted daily exposure (PDE) for the cadmium inhalation route of exposure. The updated PDE of 3 micrograms (μg)/day is based on a modifying factor approach like that used for calculating the PDEs for the cadmium oral and parenteral routes of exposure. This revised guidance is intended to correct a calculation error in the PDE for cadmium by the inhalation route of exposure.

DATES: The announcement of the guidance is published in the **Federal Register** on March 11, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: