FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, September 14, 2021 at 10:00 a.m.

PLACE: 1050 First Street NE, Washington, DC (this meeting will be a virtual meeting).

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.

Matters concerning participation in civil actions or proceedings or arbitration.

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

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2021–19597 Filed 9–7–21; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments, relevant information, or documents regarding the agreement 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 agreement 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.: 012474–002.

Agreement Name: ONE/ELJSA Space Charter Agreement.

Parties: Ocean Network Express Pte. Ltd.; and Evergreen Line Joint Service Agreement.

Filing Party: Joshua Stein; Cozen O'Connor.

Synopsis: The amendment would revise the agreement to reduce the total amount of space that will be provided by ONE to ELJSA and change the service that such space will be provided on to the FP1 service. The amendment would also revise the agreement to replace references to NYK with ONE and delete provisions of the agreement relating to the now complete transition to ONE. The parties request expedited review.

Proposed Effective Date: 10/16/2021.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1972.

Dated: September 3, 2021.

Rachel E. Dickon,

Secretary.

[FR Doc. 2021–19483 Filed 9–8–21; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0875]

S12 Nonclinical Biodistribution Considerations for Gene Therapy Products; International Council for Harmonisation; 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 ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance provides harmonized recommendations for the conduct and overall design of nonclinical biodistribution (BD) studies for gene therapy (GT) products. Considerations for interpretation and application of the BD data to support a nonclinical development program and inform the design of clinical trials are also provided. The recommendations in the guidance endeavour to facilitate the development of investigational GT products, while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles. The draft guidance is intended to promote harmonization of recommendations for BD studies for investigational GT products and facilitate a more efficient and timely nonclinical development program.

DATES: Submit either electronic or written comments on the draft guidance by November 8, 2021 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–2021–D–0875 for ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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