received within 12 days of the date this notice appears in the **Federal Register**, and the Commission requests that comments be submitted within 7 days on agreements that request expedited review. 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.: 201402.

Agreement Name: American Roll-On Roll-Off Carrier/Liberty Space Charter Agreement.

Parties: American Roll-On Roll-Off Carrier, LLC; Liberty Global Logistics LLC.

Filing Party: Bryant Gardner, Winston & Strawn LLP.

Synopsis: The Agreement would authorize the parties to discuss areas of potential cooperation and possibly engage in the purchasing of space on the vessels operated by one another for direct service or transshipment from ports and points in the United States, on the one hand, and ports and points in all other countries worldwide, on the other hand.

Proposed Effective Date: 5/8/2023.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/78502.

Dated: March 31, 2023.

JoAnne O'Bryant,

Program Analyst.

[FR Doc. 2023–07075 Filed 4–4–23; 8:45 am]

BILLING CODE 6730–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2023–0020]

Laboratory Recommendations for Syphilis Testing in the United States

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the proposed Laboratory Recommendations for Syphilis Testing in the United States. The proposed recommendations for syphilis testing include laboratory-based tests, point-of-care tests, processing of samples, and reporting of test results. The recommendations are intended to aid laboratorians and clinicians in the diagnosis of syphilis. These proposed recommendations are intended for use by clinical laboratory directors, laboratory staff, clinicians, and disease control personnel who must choose among the multiple available testing methods, establish standard operating procedures for collecting and processing specimens, interpret test results for laboratory reporting, and counsel and treat patients in the United States.

DATES: Written comments must be received on or before June 5, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0020 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Division of STD Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop US12–2, Atlanta, GA 30329, Attn: Docket No. CDC–2023–0020.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: John R. Papp, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12–3, Atlanta, GA 30329; Telephone: 404–639–8000; Email: *jwp6@cdc.gov*.

SUPPLEMENTARY INFORMATION: CDC's proposed Laboratory Recommendations for Syphilis Testing in the United States is available under the Supporting and Related Materials tab in the docket for this notice, Docket No. CDC–2023–0020, on *http://www.regulations.gov*.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions proposed in this Notice:

- Based on the evidence presented in the full recommendations document (see the Supporting and Related Materials tab in the docket), does the evidence support the proposed Laboratory Recommendations for Syphilis Testing in the United States? If not, please state the reason why and, if available, provide additional evidence for consideration.
- Are CDC's proposed Laboratory Recommendations for Syphilis Testing in the United States (see Supporting and Related Materials) clearly written? If not, what changes do you propose to make them clearer?
- If implemented as currently drafted, do you believe the proposed recommendations would result in improved laboratory testing for syphilis in the United States? If not, please provide an explanation and supporting data or evidence.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov*. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comments by email.

Background

Syphilis is a notifiable disease, with over 130,000 cases in the United States reported to the CDC in 2020 (CDC, 2020) and over 6 million new cases reported worldwide (World Health Organization, 2018). Syphilis is caused by *Treponema pallidum* subspecies *pallidum*. The United States is currently experiencing a syphilis epidemic, with sustained increases in primary and secondary syphilis. In 2000, 5,979 cases were reported; in 2020 the figure rose to 133,945 cases, a 2,140% increase (CDC, 2001, 2020). The epidemic is characterized by health disparities, particularly among sexual and gender minority populations, intersections with the HIV and substance use epidemics, and increased morbidity and mortality attributable to congenital syphilis infections (CDC, 2020). Laboratories play a critical role in the public health response to the syphilis epidemic. The responsibility of the laboratory is to test specimens and report results in a timely manner, allowing clinicians to efficiently make diagnoses and institute patient management protocols. Public health reporting by laboratories also allows local health departments and

CDC to conduct surveillance and monitoring of disease trends. CDC used current evidence to draft the proposed Laboratory Recommendations for Syphilis Testing in the United States to improve laboratory testing for syphilis and aid laboratorians and clinicians in the diagnosis of the disease.

Dated: March 31, 2023.

Tiffany Brown,

Acting Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2023–07057 Filed 4–4–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0592]

Human User Safety in New and Abbreviated New Animal Drug Applications; 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 #278 (GFI #278) entitled ''Human User Safety in New and Abbreviated New Animal Drug Applications.'' Human User Safety (HUS) is an integral component of the overall safety evaluation of proposed new animal drugs. FDA is issuing this guidance to clarify the current approaches and recommendations of FDA's Center for Veterinary Medicine (CVM) for HUS assessment and submission of HUS information to support the overall safety of proposed new animal drugs prior to approval.

DATES: Submit either electronic or written comments on the draft guidance by June 5, 2023 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–2023–D–0592 for ''Human User Safety in New and Abbreviated New Animal Drug Applications.'' 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, 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 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, 240–402–7500.

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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: Karen Sussman, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0876, *karen.sussman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #278 entitled ''Human User Safety in New and Abbreviated New Animal Drug Applications.'' This draft guidance is intended for sponsors interested in pursuing the approval, or conditional approval, of new animal drugs (including new generic animal drugs). This guidance addresses general principles of HUS assessment for new animal drugs, sources of data, mitigation strategies for proposed new animal drugs, potential recommendations to address HUS concerns, and how HUS information should be submitted to CVM.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR