DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1280]

International Conference on
Harmonisation; Electronic
Transmission of Postmarket Individual
Case Safety Reports for Drugs and
Biologics, Excluding Vaccines;
Availability of Food and Drug
Administration Regional
Implementation Specifications for ICH
E2B(R3) Reporting to the Food and
Drug Administration Adverse Event
Reporting System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the
availability of its FDA Adverse Event Reporting System (FAERS) Regional
Implementation Specifications for the International Conference on
Harmonisation (ICH) E2B(R3) Specification. FDA is making this
technical specifications document available to assist interested parties in
electronically submitting individual case safety reports (ICSRs) (and ICSR
attachments) to the Center for Drug Evaluation and Research (CDER) and the
Center for Biologics Evaluation and Research (CBER). This document, entitled
“FDA Regional Implementation Specifications for ICH E2B(R3)
Implementation: Postmarket Submission of Individual Case Safety Reports
(ICSRs) for Drugs and Biologics, Excluding Vaccines” supplements the
“E2B(R3) Electronic Transmission of Individual Case Safety Reports (ICSRs)
Implementation Guide—Data Elements and Message Specification” final
guidance for industry and describes FDA’s technical approach for receiving
ICSRs, for incorporating regionally controlled terminology, and for adding
region-specific data elements when reporting to FAERS.

DATES: Submit either electronic or
written comments on the Regional
Implementation Specifications
document at any time.

 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
• 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–1280 for “FDA Regional
Implementation Specifications for ICH
E2B(R3) Implementation: Postmarket
Submission of Individual Case Safety
Reports for Drugs and Biologics,
Excluding Vaccines.” 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
redded/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.

Submit written requests for single
copies of this 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Suranjana De, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4307, Silver Spring, MD 20993, 240–402–0498, or FAERS@fda.hhs.gov; 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

On February 21, 2014, FDA issued a Federal Register notice (79 FR 9908) announcing the availability of a final guidance for industry entitled “E2B (R3) Electronic Transmission of Individual Case Safety Reports (ICSRs) Implementation Guide—Data Elements and Message Specification” (ICH E2B(R3) guidance) and an appendix to the guidance entitled “ICSRs: Appendix to the Implementation Guide—Backwards and Forward Compatibility” (BFC appendix). The ICH E2B(R3) guidance and BFC appendix were issued as a package that included schema files and additional technical information to be used for creating compatible ICSR files. The preface to the ICH E2B(R3) implementation guidance makes clear that any future “technical specifications document associated with that guidance would be provided as a stand-alone document” but incorporated by reference into that guidance. Accordingly, in this notice, we are announcing the availability of a technical specifications document that will be incorporated into that final guidance.

This technical specifications document, which is available on the FDA Guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm274966.htm, is to assist interested parties in electronically submitting individual case safety reports (ICSRs) (and any ICSR attachments) to CDER and CBER. This document describes FDA’s technical approach for submitting ICSRs, for incorporating its regionally controlled terminology, and for adding its regional data elements that are not addressed in the ICH E2B (R3) guidance for the following FDA-regulated products: Drug products marketed for human use with approved new drug applications and abbreviated new drug applications; prescription drug products marketed for human use without an approved application; non-prescription (over-the-counter) human drug products marketed without an approved application; and biological products marketed for human use with approved biologic license applications.

II. Electronic Access


Dated: June 17, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–14845 Filed 6–22–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–0374]

Waterway Suitability Assessment for Construction and Operation of Liquefied Gas Terminals; Sabine-Neches Waterway, Vidor, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: Jefferson Railport Terminal 1 (Texas) LLC, has submitted a Letter of Intent and Preliminary Waterway Suitability Assessment to the Coast Guard Captain of the Port (COTP), Port Arthur, TX regarding the company’s plans to construct, own and operate a waterfront facility handling and storing Liquefied Hazardous Gas (LHG) at its Vidor, TX facility located on the Sabine-Neches Waterway. The Coast Guard is notifying the public of this action to solicit public comments on the proposed increase in LHG marine traffic on the Sabine-Neches Waterway.

DATES: Comments must be submitted to the online docket via http://www.regulations.gov or reach the Docket Management Facility, on or before July 25, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0374 using the Federal eRulemaking Portal at http://www.regulations.gov. See the “Public Participation and Request for Comments” portion of the SUPPLEMENTARY INFORMATION section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For further information about this notice, call or email Chief Petty Officer Jamie L. Merriman, U.S. Coast Guard; telephone 409–719–5033, email jamie.l.merriman@uscg.mil.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments or related material in response to this notice. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. We encourage you to submit comments through the Federal eRulemaking Portal at http://www.regulations.gov. Your material cannot be submitted using http://www.regulations.gov. contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at http://www.regulations.gov and can be viewed by following that Web site’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to http://www.regulations.gov and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the Federal Register (70 FR 15086).

Discussion, Basis, and Purpose

Under 33 CFR 127.007(a), an owner or operator planning to build a new facility