

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-N-1548]

Invitation To Participate in Account Management Pilot for the Import Trade Auxiliary Communication System**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to conduct a pilot program to test and evaluate a new Import Trade Auxiliary Communication System (ITACS) Account Management function. Participation will be needed from a small group of Filers, Importers of Record, and Consignees, who will use the new ITACS Account Management function and provide feedback to FDA. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email.

DATES: To be considered for participation in this ITACS pilot, please send an email with the subject line "ITACS Pilot Participation Request" by July 7, 2016.

ADDRESSES: Submit pilot participation request emails to FDA's ITACS Support at itacssupport@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Sandra Abbott, Division of Compliance Systems, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852-1740, 301-796-3240, itacssupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

ITACS currently provides the import trade community with four functions: (1) The ability to check the status of FDA-regulated entries and lines, (2) the ability to submit entry documentation electronically, (3) the ability to electronically submit the location of goods availability for those lines targeted for FDA physical examination, and (4) the ability to check the estimated laboratory analysis completion dates. No user login accounts are necessary to access these functions; all that is necessary is a valid customs entry number that has been successfully transmitted to FDA. FDA has developed, and wishes to test, an ITACS user account management function.

II. Description and Conditions of the Pilot Program

The purpose of this pilot is to test and evaluate a new ITACS account management function.

This pilot will not impact the availability of current functionality of ITACS. Rather, it will provide FDA and a small group of volunteers with the opportunity to test expanded functionality of ITACS, specifically the use of user login accounts. User login accounts enable FDA to distribute Notices of FDA Action to users electronically via email (rather than regular mail) and enable users to download Notices of FDA Action from within ITACS. User login accounts also allow users to view in ITACS the details of specific information requests, which are currently delivered via hard copy Notices of FDA Action. Implementation of user login accounts would also allow for potential future ITACS enhancements, requested by the import trade community, that require user authentication.

Pilot participants should be prepared to commit to: (1) Attending a kickoff training session, using the new functionality, (2) providing real-time feedback, and (3) participating in any followup meetings FDA deems necessary over the course of the pilot period. Pilot participants should also be willing to receive their Notices of FDA Action electronically in lieu of FDA distribution of paper Notices of FDA action.

III. Duration

FDA currently anticipates the pilot to begin in July 2016 and to last through October 2016. However, these dates are subject to change. A more definitive schedule will be determined after FDA has selected volunteers. FDA will contact selected volunteers via email within 2 weeks of the closure of the solicitation period.

IV. How To Apply for Participation in the Pilot

To be considered for participation in this ITACS pilot, please send an email with the subject line "ITACS Pilot Participation Request" to itacssupport@fda.hhs.gov by July 7, 2016. Please limit participation requests to one individual per firm at the corporate level. That person should be a high-ranking individual within the firm who could have the capability to create and manage ITACS accounts for other users at different locations within the same firm. FDA expects to select nine or fewer participants for this pilot program.

Please include the following information in your pilot participation request email:

- Your name, position, and contact information including email;
- your firm's name and address; and
- your firm's role in the importation of FDA-regulated entries (Filer, Importer of Record, Consignee, or any combination thereof).

FDA will contact volunteers selected for participation in the pilot program via email within 2 weeks of the closure of the solicitation period.

Dated: June 17, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-14874 Filed 6-22-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2016-N-0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Amendment of Notice**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of June 16, 2016. The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: ODAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 16, 2016, 81 FR 39274, FDA announced that a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee would be held on June 28 and 29, 2016. On page 39274, in the third column, the *Procedure* portion of the document is changed to read as follows:

FDA regrets that it was unable to publish this notice 15 days prior to the June 28 and 29, 2016, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting. Because the Agency believes there is some urgency to bring these issues to public discussion and qualified members of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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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 ICSR, 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 posted on <http://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):** 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 redacted/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,