• User experience and evaluation of current processes and tools and their effects on organizational performance;
• Needs and specifications for proposed new tools and processes;
• Business processes driving the development of information systems; and
• The effect of processes and tools on problem solving quality, efficiency, and cost.

All abstracts must be received by February 15, 2013, and authors whose posters have been accepted will be notified by February 28, 2013.

The conference will make available an exhibition hall. The exhibitor price for this conference is $3,500. Neither PhUSE nor FDA endorse any commercial software or vendor.

Dated: February 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03324 Filed 2–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Global Quality Systems—An Integrated Approach To Improving Medical Product Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Cincinnati District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public workshop entitled ''Global Quality Systems—An Integrated Approach to Improving Medical Product Safety.'' This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: The public workshop will be held on June 10 and 11, 2013, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Louisville Marriott Downtown, 280 West Jefferson St., Louisville, KY, 502–627–5045 or toll-free 800–533–0127; *http://www.marriottlouisville.com/.*

Attendees are responsible for their own accommodations. To make reservations at the Louisville Marriott Downtown, at the reduced conference rate, contact the Louisville Marriott Downtown before May 2, 2013, and cite meeting code ''AFDO Conference.''

FOR FURTHER INFORMATION CONTACT: Krystal Reed, Association of Food and Drug Officials, 2550 Kingston Rd., suite 311, York, PA 17402, 717–757–2888, FAX: 717–650–3650, *email: kreed@afdo.org.*

SUPPLEMENTARY INFORMATION:

Registration: You are encouraged to register by May 14, 2013. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration is as follows:

COST OF REGISTRATION

Member	$450.00
Non-Member	$550.00
To be added to registration fee for registration postmarked after May 14, 2013	$100.00

If you need special accommodations due to a disability, please contact Krystal Reed (see **FOR FURTHER INFORMATION CONTACT**) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO.'' Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org/conference.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org*

The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

• Future of Combination Product Regulation.
• Unique Device Identifier Progress.
• Health Canada Update.
• The Safety of our Drugs and Devices—the Complex Reality.
• Nanotechnology.
• Drug and Medical Device Trends.
• Case for Quality (Center for Devices and Radiological Health) Presented by Steve Silverman.
• Working Luncheon Interactive Session—Lessons Learned From the Mistakes of Others.
• Complaint Handling—It's Not Just About Compliance—It's an Effective Business Driver.
• FDA's Cosmetic Regulatory Agenda.
• Challenges With Implementation of U.S.P. 35 on a Global Basis.
• Pilot Program for Abbreviated Drug Inspections.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03323 Filed 2–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0724]

Documents To Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following revised final versions of documents that support making regulatory submissions in

electronic format using the electronic Common Technical Document (eCTD) specifications: ''The eCTD Backbone Files Specification for Module 1, version 2.1'' (which includes the U.S. regional document type definition, version 3.1), and ''Comprehensive Table of Contents Headings and Hierarchy, version 2.1.'' Technical files that support these documents are also available on the Agency Web site. A complete summary of the revisions made is included in the updated documents. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT:
Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1105, Silver Spring, MD 20993, 301–796–1065, *constance.robinson@fda.hhs.gov*; or
Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 11400 Rockville Pike, HFM–165, rm. 4155, Rockville, MD 20857, 301–827–1332, *joseph.montgomery@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003; the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, provide clarification of business rules for submission processing and review, refine the characterization of promotional marketing and advertising material, and facilitate automated processing of submissions. FDA announced availability of final versions of technical documentation in the **Federal Register** of August 6, 2012 (77 FR 46763). FDA has revised the final documentation and is making available revised versions of the following documents:

- ''The eCTD Backbone Files Specification for Module 1, version 2.1,'' which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions,'' which will be revised as part of the implementation of the updated eCTD backbone files specification.
- ''Comprehensive Table of Contents Headings and Hierarchy, version 2.1,'' which reflects updated headings that are specified in the document entitled ''The eCTD Backbone Files Specification for Module 1, version 2.1.''

Supporting technical files are also being made available on the Agency Web site.

A complete summary of the revisions made are included in the updated documents. The revisions include the following:

- The 1.16 heading regarding risk management was modified and subheadings were added.
- The application-type attribute file was modified to include PMA and 510(k).
- Attribute files were modified to allow the version, date, and number to be machine readable.

FDA is not prepared at present to accept submissions utilizing this new version, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm, http://www.regulations.gov*, or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03319 Filed 2–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Ryan White HIV/AIDS Program (Part C) Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide one-time noncompetitive Part C funds to the Hoboken Community Healthcare, Inc., Hoboken, New Jersey.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is $327,166.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. § 300ff–51.

CFDA Number: 93.918.

Project period: The period of support for this award is from January 1, 2013, through June 30, 2013.

Justification for the Exception to Competition: Hoboken Municipal Hospital Authority (HMHA), Hoboken, NJ; H76HA07886 announced the December 31, 2012, relinquishment of their Part C grant to Hoboken Community Healthcare, Inc., a nonprofit 501(c)(3) organization that purchased the hospital and associated clinics. Hoboken Community Healthcare, Inc. has been identified as an interim provider of the Part C grant. The amount of $327,166 will be awarded to Hoboken Community Healthcare, Inc., which represents a proportional share of the last award to HMHA. This funding will support HIV medical care until the start of a new funding cycle under HRSA–13–168 with a July 1, 2013, start date.