

harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: <http://www.ich.org>.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Public oral presentations will be scheduled between approximately 4 p.m. and 4:30 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by 5 p.m. e.s.t. on October 11, 2010, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, telephone number, fax, and email of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available on the Internet at: <http://www.fda.gov/Drugs/NewsEvents/ucm225322.htm>.

Dated: September 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0486]

#### Safe Use Initiative; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop entitled "Safe Use Initiative." This public workshop, organized and hosted by FDA's Safe Use Initiative Team, will communicate the status of ongoing activities and the future vision for Safe Use Initiative projects. The workshop will also offer an opportunity for the Safe Use Initiative Team to gather input and perspectives for future directions and develop collaborative, cross-sector safe medication use activities with health care stakeholders.

**DATES:** The public workshop will be held on November 16, 2010, from 8:30 a.m. to 4:45 p.m., and November 17, 2010, from 8:30 a.m. to 12 noon. Suggestions for safe use topics received by October 15, 2010, may become the focus for indepth discussions during the workshop breakout sessions held the afternoon of November 16, 2010 (see section II of this document). Electronic or written comments will be accepted until January 31, 2011 (see section IV of this document).

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993-0002.

Submit electronic comments on this document to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Sharon Bakayoko, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1353, Silver Spring, MD 20993-0002, 301-796-7600, [CDERSafeUseInitia@fda.hhs.gov](mailto:CDERSafeUseInitia@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The mission of the Safe Use Initiative is to reduce preventable harm from FDA-regulated medications. The Safe

Use Initiative seeks to create and facilitate public and private collaborations aimed at reduction of preventable harm.

FDA announced the "FDA's Safe Use Initiative—Collaborating to Reduce Preventable Harm From Medications" (the Safe Use Report) on November 5, 2009 (74 FR 57319). The Safe Use Report calls for an open and transparent process with health care stakeholders to identify candidate drug/drug classes or therapeutic areas that could benefit from a collaborative approach to harm reduction.

The first steps in public engagement involved outreach to the health care community—through public meetings, teleconferences, and listening sessions with stakeholder groups (e.g., health care professionals, consumer groups, insurers, and industry). The goals were to inform organizations about the Safe Use Initiative, to obtain feedback about medication safety and preventable medication harm, and to seek opportunities for collaboration. The suggestions that emerged from the safe use outreach activities ranged from preventing a specific drug-related adverse event to broad and overarching themes in health care.

##### II. Scope of the Public Workshop

This public workshop expands the Safe Use Initiative outreach efforts. It will provide a forum to engage the health care community about collaborations, interventions, and metrics for ongoing and future projects to make medications safer.

We are soliciting input in advance of the public workshop about topics for potential safe use collaborations. FDA will consider all topics. However, if submitted by October 15, 2010, some topics may become the focus for more indepth discussions and partnership development during the public workshop. Please submit topic suggestions (identified with the docket number found in brackets in the heading of this document) to the Division of Dockets Management (see **ADDRESSES**). When submitting a topic for consideration, please suggest how it could become a safe use project, e.g., other health care partners who might have an interest in the issue, kinds of interventions to reduce preventable harm, metrics, etc.

##### III. Attendance and Registration to Speak

The FDA Conference Center at the White Oak location is a Federal facility with security procedures. There is no fee to attend the workshop, and attendees who do not wish to make an

oral presentation do not need to register. Seating is limited and will be on a first-come, first-served basis.

If you would like to make an oral presentation during the public session on November 17, 2010, you must register and provide an abstract of your presentation by the close of business on October 15, 2010. To speak, submit your name, title, business or organization affiliation (if applicable), address, telephone number, fax number, and email address to Sharon Bakayoko (see **FOR FURTHER INFORMATION CONTACT**). FDA has included areas of interest in section II of this document. Please indicate the topic area you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interest are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should check in at the registration desk before the workshop. Time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage electronic or written comments to the docket (see section IV of this document).

If you need special accommodations because of a disability, please contact Sharon Bakayoko at least 7 days before the workshop.

#### IV. Comments

Regardless of attendance at the workshop, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document, including suggestions for workshop topics. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Information about the Safe Use Initiative, including the Safe Use Report, is available on the Internet at <http://www.fda.gov/safeuseinitiative>. Information about the workshop will be posted on this Web site when it is available.

#### VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.fda.gov/safeuseinitiative> and <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: September 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### Part D Grant for Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth Part D Funds Under the Ryan White HIV/AIDS Program

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notice of Non-competitive Award of Part D Funds for the University of Utah.

**SUMMARY:** HRSA will be awarding, non-competitively, Part D Funds to support family-centered primary medical care, treatment, and support services (directly or through contracts) for women, infants, children, and youth with HIV/AIDS, to the University of Utah in order to ensure continuity of critical HIV medical care and support services, to women, infants, children and youth in Salt Lake City, Utah and the surrounding counties.

##### SUPPLEMENTARY INFORMATION:

*Grantee of record:* Utah Department of Health, Salt Lake City, Utah.

*Intended recipient of the award:* University of Utah, Salt Lake City, Utah.

*Amount of the award:* \$350,000 to ensure continuity of medical care and support services to the target population.

**Authority:** Section 2671 of the Public Health Service Act, 42 U.S.C. 300ff-71.

*CFDA Number:* 93.918.

*Project period:* August 1, 2010, to July 31, 2011. The period of support for this award is from August 1, 2010, to July 31, 2011.

#### Justification for the Exception to Competition

Funding for critical HIV medical care and support services to women, infants, children and youth in Salt Lake City, Utah and the surrounding areas will be continued through a non-competitive award to the University of Utah. The Utah Department of Health is currently contracting all of these services to the University of Utah. The University of Utah has the clinical, fiscal, and administrative infrastructure to administer the Part D Grant since it is currently the Part C Early Intervention Services Grant recipient. This is a temporary replacement award, as the previous grant recipient serving this population notified HRSA that it could not continue as the grantee of record after July 31, 2010. HRSA's HIV/AIDS Bureau identified the University of Utah as the best qualified entity for this temporary grant. Since the grant's inception, the Utah Department of Health has contracted with the University of Utah to provide all Part D services, and the University can continue to ensure family-centered care involving outpatient or ambulatory care (directly or through contracts) for women, infants, children, and youth living with HIV/AIDS. The University is able to provide critical services with the least amount of disruption to the service population while the service area is re-competed.

This supplement will cover the time period from August 1, 2010, through July 31, 2011. This service area will be included in the upcoming competition for the Part D Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth for project periods starting August, 2011.

**FOR FURTHER INFORMATION CONTACT:** Dora Ober, by e-mail [dober@hrsa.gov](mailto:dober@hrsa.gov), or by phone, 301-443-0759.

Dated: September 15, 2010.

**Mary K. Wakefield,**

*Administrator.*

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