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, HHSS.

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 OVER THE LAST YEAR

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.

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.