(4) Increase information dissemination and training, and

(5) Improve coordination across the radiological health community.

II. Agenda

On October 31, 2005, FDA is providing the opportunity for a number of stakeholder organizations to discuss how they can assist FDA in implementing the program and in addressing important public health problems. FDA and its stakeholders will discuss the following aspects of the radiological health plan overview:

• Standards—Discussion will consider the following topics: Increased reliance by FDA on consensus radiation safety performance standards, the role of national and international standards, and the role of State regulations in assuring product safety and proper use.

• Monitoring the Use of Radiation—Discussion will consider the following topics: The shift of CDRH's focus from products to users, patients, and consumers; adverse event reporting; State program roles in ensuring appropriate use of radiation; facility quality assurance programs; and the establishment of a voluntary patient radiation dose reporting system for diagnostic imaging procedures that use ionizing radiation. This system could be used to monitor national exposure trends and provide a basis for establishing diagnostic reference levels of patient dose for use in facility quality improvement programs.

• Monitoring the Industry—Discussion will consider the following topics: The shift of FDA emphasis from testing products, to inspecting manufacturers to assure quality manufacturing and products; the reduction of reporting requirements; and the development of electronic reporting methods.

• Education—Discussion will consider education and training for manufacturers, regulators, and users.

On November 1, 2005, FDA will hold concurrent discussion sessions throughout the day on the Standards, Monitoring, and Education topics to provide further opportunity for stakeholder comment and discussion.

FDA will provide an opportunity for comment during the public comment period for individuals and/or organizations on October 31, 2005. In addition, the agency will provide an opportunity to present individual viewpoints during the concurrent discussion sessions on November 1, 2005. FDA reserves the right to limit the time of speakers during the public comment periods.

III. Registration

Participants must register for the meeting by October 17, 2005. Acceptance will be on a first-come, first-served basis. There will be no onsite registration and unregistered participants will not be added to the program. Please register online at *http://www.fda.gov/cdrh/meetings/120303.html*. Persons without Internet access may register for the onsite meeting by calling 301–594–3309 by October 17, 2005.

If you need special accommodations due to a disability, please fax information regarding those needs to Kaye Chesemore at 301–594–3306, at least 7 days in advance of the meeting.

IV. Request for Suggestions, Recommendations, and Materials

FDA is particularly interested in receiving suggestions from stakeholders related to the topics listed previously in this document. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**).

FDA will place an additional copy of any material it receives in the docket for this document (2005N–0375). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday (see **ADDRESSES**).

V. Transcripts

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see **ADDRESSES**).

Dated: September 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19077 Filed 9–20–05; 3:31 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8000]

Memorandum of Understanding Between the Food and Drug Administration and the Food and Drug Administration Alumni Association

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the Food and Drug Administration Alumni Association, Inc. The purpose of this MOU is to establish a greater collaboration between FDA and the Food and Drug Administration Alumni Association, Inc., regarding FDAs 2006 Centennial Observance.

DATES: The agreement became effective July 28, 2004.

FOR FURTHER INFORMATION CONTACT: Mary Hitch, Senior Advisor, Office of External Relations (HF–10), 5600 Fishers Lane, Rockville, MD 20857, 301–827–4406.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-04-8000

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION

AND THE

FOOD AND DRUG ADMINISTRATION ALUMNI ASSOCIATION, INC.
AGREE TO CO-SPONSOR FDA'S 2006 CENTENNIAL OBSERVANCE
ACCORDING TO THE TERMS EXPRESSED BELOW:

Background

On June 30, 2006, the Nation will celebrate the 100th anniversary of the enactment of the Pure Food and Drugs Act. The centennial anniversary offers a unique opportunity to work with the Food and Drug Administration Alumni Association, Inc. (FDAAA) and other groups to broaden public awareness of the Food and Drug Administration's (FDA) wide-ranging responsibilities in order to enhance its capacities to carry out its mission in the new millennium.

This agreement is between the U.S. Department of Health and Human Services (HHS), FDA, and the FDAAA -- Taxpayer Identification Number 41-2051166. In March 2003, FDA and FDAAA entered into a Memorandum of Understanding (MOU) to partner on future specific undertakings that are considered beneficial to both organizations, are directly related to the mission of FDA, and are within FDA's statutory authorities. In accordance with the MOU, it is understood that FDA and FDAAA may work together on future efforts and that FDA and FDAAA will formalize such activities in specific agreements, such as this Co-sponsorship agreement that set forth the responsibilities of each party in co-sponsoring FDA's 2006 Centennial Observance.

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation.

The FDAAA is an incorporated 501(c)(3) educational public service organization dedicated to supporting the mission of FDA and to advancing its goals of protecting and promoting the public health.

FDA and the FDAAA have common interests in collaborating on various programs and materials for FDA's 2006 Centennial Observation. Through this collaboration, FDA and FDAAA hope to:

- Broaden public awareness of FDA's services and programs and thereby increase public appreciation of FDA's impact on public health and safety;
- Commemorate the first 100 years of contributions to health in America and the worldwide community;

- Inspire the next generation of science, innovation, and public health, and strengthen FDA's capacity to meet future challenges; and
- Recognize contributions of FDA employees, legislators, academicians, industry, advocacy groups, and public health leaders who support FDA's mission.

Responsibilities for Developing the Event

FDA and FDAAA agree to collaborate on developing various events in celebration of FDA's 2006 Centennial Observances related to the mission of FDA. FDA and FDAAA may independently sponsor portions of the Centennial Observance. FDA resources, including staff, shall not be used to develop, promote, or otherwise support any portion of independently supported events. Official announcements and brochures associated with those events may contain factual references to the schedule of the entire event, including portions supported by private donors.

Registration Fees and Other Charges

FDAAA shall not charge fees higher than necessary to recover its share of the costs of the Centennial Observance. FDAAA intends to sell educational materials about the Centennial. All educational materials, transcripts, and recordings of the events shall be sold at cost. As discussed at the June 28, 2004, meeting, FDA employees will be charged a nominal fee for these materials like others to defray costs.

Fundraising

FDAAA shall make clear, in all FDAAA's solicitations of funds from private donors, that it is FDAAA, not FDA, that is asking for any funds to cover its share of the Centennial Observance costs. FDAAA shall not imply that FDA endorses any FDAAA fund-raising for the Centennial Observance. FDAAA will make clear to donors that donations shall be applied exclusively toward defraying the expenses of FDAAA, and not FDA.

Promotional Activity

FDAAA shall not use the event mainly as a way to sell or promote products or services. FDAAA shall ensure that any incidental promotions do not imply that FDA endorses FDAAA's actions or messages. FDAAA shall make reasonable efforts, subject to FDA review, to separate any incidental promotions from the approved Centennial programs, events, and materials. Donors who are public officials or candidates for public office will not include political comment as part of their participation. Donors who have a preexisting business relation with FDA shall be informed that their donations will not result in special consideration by FDA on any other matter.

All Centennial Observance materials bearing the FDA name, logo, or HHS Seal must display the authorization number, be approved in advance by FDA, and contain the following statements: (1) "FDA's participation in this co-sponsorship is not an approval of the views, opinions, products or services of any co-sponsor or other person or entity;" (2) "All FDA programs or co-sponsored programs are extended to the public on a nondiscriminatory basis;" and (3) "Reasonable arrangements for anyone with disabilities shall be made if requested at least 2 weeks in advance."

FDAAA is responsible for: 1) soliciting any advertisement, 2) general layout and event preparations, 3) collection of advertising fees, and 4) payment of all production expenses. FDAAA may not receive or benefit from any funds associated with advertisements or production of the Centennial Observance. FDAAA must avoid advertising solicitations from organizations focused on gaming, alcoholic beverage, or tobacco. FDAAA shall not use the FDA name to imply that FDA endorses products or services of any entity. FDA may help compile information, prepare articles, and distribute publications.

Event Publicity and Endorsements

FDA requires appropriate recognition for its co-sponsorship of Centennial Observance and educational material used or distributed. Within reasonable discretion, FDA retains the right to decide what constitutes appropriate recognition. FDAAA will not use the name of FDA, except in factual publicity for the Centennial Observance and associated materials. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the Centennial Observance. Such factual publicity shall not imply FDA's endorsement of any of the opinions, products, or services of any donor. Where confusion could result, a disclaimer should clearly state that no endorsement is intended. FDAAA will clear all publicity materials for the event with FDA to ensure compliance with this paragraph. There will be no promotion of individual products or services of FDAAA, or of any donor or contractor involved in FDA's Centennial Observance.

Records

FDA and FDAAA shall maintain records that account fully and accurately for the financial commitments and expenditures of FDA and FDAAA for the 2006 Centennial Observance. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

Public Availability

This co-sponsorship agreement, as well as the financial records maintained by the parties, shall be publicly available.

Amendments

This agreement can only be amended in writing, and all parties to this agreement who are affected by it must agree to any amendment.

Effect and Termination

This agreement is effective on the date of approval and will continue until close of business on February 28, 2007. Any party may terminate its participation in the co-sponsorship by providing written notice to the other party. Such termination will not require changes to materials already produced, and will not entitle the terminating party to a return of funds or property contributed.

Contacts

Lawrence L. Bachorik, Ph.D.
Acting Associate Commissioner for External Relations
Food and Drug Administration

James S. Benson, Chair
Food and Drug Administration Alumni Association, Inc.
Ad hoc Committee on the FDA Centennial

Co-Sponsorship Guidance

FDA and FDAAA will abide by the legal memorandum of August 8, 2002, entitled "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official. See attachment.

Approval

Each person approving this agreement is sanctioned to enter this agreement on behalf of their respective organization. Except as properly amended, this agreement is the final and complete agreement of FDA and FDAAA.

Food and Drug Administration:

Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner for Food and Drugs — Date 07/22/04

Food and Drug Administration Alumni Association:

Mr. John Villforth, Chairman, FDAAA Board of Directors — Date 07-28-04

[FR Doc. 05–19016 Filed 9–22–05; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[CFDA 93.223]

Cooperative Agreement for Border Health Best Practices

AGENCY: Office of Rural Health Policy, HRSA, DHHS.

ACTION: Notice of Single Source Award.

SUMMARY: The Office of Rural Health Policy (ORHP), in cooperation with the Office of Global Health Affairs (OGHA), Office of Minority Health (OMH), Office on Women's Health (OWH), and Centers for Disease Control and Prevention (CDC) will award a one year single source award to the U.S.-Mexico Border Health Association (USMBHA) to identify and promote best practices in border communities. As defined in the La Paz Agreement, the border region is 100 km north and south of the international boundary line between the United States and Mexico. Funds will be used on both sides of the U.S.-Mexico border for the development of activities under the second annual Border Binational Health Week (October 10–16, 2005).

FOR FURTHER INFORMATION CONTACT: Elizabeth Rezai-zadeh, Office of Rural Health Policy, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–443–4107. E-mail: *erezai@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award

U.S.-Mexico Border Health Association in El Paso, TX.

Amount of the Award

$383,000.