

take to reduce those barriers while assuring the safety, effectiveness, and quality of medical devices marketed in the United States.

The Council seeks input from a wide range of constituencies to include but not be limited to industry, academia, patient/consumer advocacy groups, professional organizations, and other State and Federal bodies under aligned public health missions, to address the issues outlined in this document.

During the public workshop, there will be an open dialogue between Federal Government Council members and experts from the private and public sectors regarding the topics described in this document. Workshop participants will not be expected to develop consensus recommendations, but rather to provide their perspectives on priority areas in which medical device innovations can have the highest positive impact on public health. Participants will also be encouraged to comment on devices not being developed or redesigned due to barriers that the Federal Government can and should directly or indirectly remove or minimize.

Additional information on the public workshop, including an agenda, will be made available in advance of June 24, 2010, at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

II. Public Participation

If you wish to make an oral presentation during the public workshop, you must indicate this at the time of registration. There are two types of opportunities for participation planned for the public workshop. In one, formal presentations will address one of the two topics (see section III of this document) that will be limited to 15 minutes and require submission of the presentation in advance of the meeting. The other will be time-limited, based on the number of requests, as part of the public comment period. When registering, you will be required to identify the title of the topic you wish to address in your presentation and answer all the related questions on the web registration form. FDA will do its best to accommodate requests to present and will focus discussions to the topics described in this document (see section III of this document). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for joint presentations. FDA will determine the amount of time allotted to each

presenter and the approximate time that each oral presentation is to begin.

III. Issues for Discussion

The workshop will focus on three topics: (1) Identification of the most important unmet public health needs; (2) delineation of the barriers to the development, redesign, and patient and healthcare professional access to medical devices that can cure, significantly improve, or prevent these illnesses or injuries; and (3) identification of the actions the Federal Government can take to remove or minimize these barriers. The discussion of these general topics should not be limited by current statutes or regulations and will include, but not be limited to, discussion of the following questions:

1. Identifying areas of public health need:
 - a. Which unmet public health needs could be most effectively addressed by the development of new, or the redesign of existing, medical devices?
 - b. How should the Council set priorities amongst the identified public health needs? Are there specific factors that should be considered? If so, which and why?
2. Addressing barriers to development and/or redesign of medical devices:
 - a. What are the significant barriers facing innovators, academics, and/or industry that limit the availability and clinical use of medical devices that have the potential to improve public health?
 - b. How should any perceived or actual barriers be evaluated to determine whether federal intervention is appropriate?
 - c. How should federal agencies—including those present and others not represented—address those barriers that are out of proportion to what is warranted based on the public health needs?

IV. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

Dated: May 20, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-12588 Filed 5-25-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance, Natural History, Quality of Care and Outcomes of Diabetes Mellitus with Onset in Childhood and Adolescence, RFA DP 10-001, Initial Review

Correction: This notice was published in the **Federal Register** on March 22, 2010, volume 75, Number 54, Page 13560. The Place and time should read as follows:

Time and Date: 8:30 a.m.–6 p.m., June 15, 2010 (Closed).

Place: W Hotel, 3377 Peachtree Road, NE., Atlanta, GA 30326, Telephone: 678-500-3100.

Contact Person for More Information: Donald Blackman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-3023, E-mail: DBY7@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2010.

Andre Tyler,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-12627 Filed 5-25-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0004]
[FDA 225-09-0012]

Memorandum of Understanding Between the Food and Drug Administration and Drugs.Com

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 Drugs.Com. The purpose of the MOU is to extend the reach of FDA Consumer Health Information and to provide consumers with better information and timely content concerning public health and safety topics, including alerts of

emerging safety issues and product recalls.

DATES: The agreement became effective May 26, 2010.

FOR FURTHER INFORMATION CONTACT: Jason Brodsky, Consumer Health Information Staff, Office of External Relations, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5378, Silver Spring, MD 20993-0002, 301-796-8234, e-mail: Jason.Brodsky@fda.hhs.gov.

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: May 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

MOU Number: 225-09-0012

MEMORANDUM OF UNDERSTANDING
between
THE FOOD AND DRUG ADMINISTRATION
and
DRUGS.COM

I. PURPOSE AND GOALS

This Memorandum of Understanding (“MOU”) establishes a cooperative public education program between two entities (individually a Party -- collectively the Parties): The Food and Drug Administration (FDA), Office of External Relations (OER), Consumer Health Information Staff and Drugs.com.

The purpose of the cooperative program is to:

- extend the reach of FDA Consumer Health Information; and
- provide consumers with better information and timely content concerning public health and safety topics, including alerts of emerging safety issues and product recalls.

II. AUTHORITY

This MOU is authorized pursuant to section 903 of the Food, Drug and Cosmetic Act (21 USC 393(d)(2)).

III. BACKGROUND

The Parties have entered into this Agreement in mutual recognition of the need to empower consumers with health information they can apply in everyday life.

The FDA Web site currently receives approximately 6 million visitors per month, most of which are representatives of regulated industry. Within the agency’s site, FDA Consumer Health Information receives approximately 250,000 page views per month. Drugs.com is visited by 11 million individuals each month proactively seeking information on medications. Drugs.com’s mission is to empower patients with the knowledge to better manage their own healthcare and to improve safety by assisting in the reduction of medication errors.

This MOU meets the requirements set forth in FDA’s policy statement on co-branding of FDA Consumer Health Information, which is available online at <http://www.fda.gov/ForConsumers/ucm126390.htm>.

FDA and Drugs.com recognize that this partnership agreement is not intended, and may not be relied on, to create any right or benefit, substantive or procedural, enforceable by law by any party against the United States or against Drugs.com.

IV. PROGRAM COMPONENTS AND ACTIVITIES

The components and activities of the Program are expected to increase FDA’s capacity to disseminate time-sensitive public health information. The cooperative public education program will include the following components:

- An FDA/Drugs.com joint online resource on the Drugs.com site (the “Program”), which will feature editorial and visual FDA Consumer Health Information such as videos and photo slideshows. The parties will mutually agree to the type and exact items of content made available through the Program and on other parts of Drugs.com As a general matter, the Program

will feature a minimum of 50 articles of FDA content and provide users with access to the agency's full catalog of Consumer Updates. Drugs.com will promote the Program throughout their site and within interactive tools.

- Integration of FDA Consumer Health Information with Drugs.com's mobile phone platform, which currently receives approximately 140,000 visitors per month.

V. TERMS OF THE MOU

1. FDA Consumer Health Information must be easily distinguishable from non-FDA content within the Program. Placement of FDA Consumer Health Information within the Program should be clearly identified as such. Examples of clearly identifying FDA Consumer Health Information would be placing this information in a box and/or using a distinct color to distinguish it from non-FDA content, and/or otherwise clearly distinguishing the non-FDA content via an adequate disclaimer statement.
2. Printed and online Web pages containing FDA Consumer Health Information must be free of advertisements to avoid implying FDA's endorsement or support for a particular product, service or Web site.
3. This MOU does not grant exclusivity to either party. Neither party is restricted from participating in similar initiatives with other public or private agencies, organizations or individuals.
4. All activities within the scope of this Agreement must comply with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998 (see HHS policy on Section 508 compliance at <http://www.hhs.gov/od/508policy/index.html>); and Office of Management and Budget (OMB) policies for protecting private information (see www.usa.gov/webcontent/reqs_bestpractices/laws_regs/privacy.shtml).
5. FDA and Drugs.com will cooperate in maintenance of each party's trademarks and logos. The FDA will not permit use of its logo for marketing purposes other than to promote the Program. The use of FDA names or logos shall not imply any exclusive arrangement. Any use of FDA logos must be approved, in advance, by FDA's Consumer Health Information Staff.
6. Both parties agree that information FDA provides to Drugs.com shall be public domain material. FDA shall have full rights to reuse the content for all FDA purposes, and the right to share with other collaborators or requestors.
7. Drugs.com agrees to maintain current FDA Consumer Health Information within the Site and Program. FDA Consumer Health Information must be removed from the Program in the following circumstances: (1) within 3 years of the date of its first publication; (2) upon termination of this Agreement, if the partnership Agreement terminates less than 3 years after the material is posted; (3) upon FDA's request in circumstances in which the information becomes outdated; or (4) as soon as commercially practicable but no longer than 72 hours after receipt of a written request from FDA to remove the material, regardless of reason. Drugs.com's failure to display current FDA Consumer Health Information may result in the termination of this Agreement.
8. This Agreement does not and is not intended to transfer to either party any rights in any technology or intellectual property.

V. LINKS

FDA and Drugs.Com will provide inbound and outbound links to and from the Program and the FDA's Consumer Health Information Web page.

FDA will not provide Drugs.com access to any document or information to the extent that providing such access would place the FDA in breach of the Trade Secrets Act, codified at 18 U.S.C. sec. 1905; the Privacy Act, codified at 5 U.S.C. sec. 552a; the Food, Drug, and Cosmetic Act, codified at 21 U.S.C. sec. 301, et seq (particularly 21 U.S.C. sec. 331(j)); FDA regulations (21 Code of Federal Regulations (CFR)); or any other Federal law or regulation.

VI. LIAISON OFFICERS

Jason Brodsky
Director, Consumer Health Information Staff
Office of External Relations
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15A-29
Rockville, Maryland 20857
PHONE: 301-827-6251
E-mail: Jason.Brodsky@fda.hhs.gov

Philip Thonton
Chief Executive Officer
Drugs.com
P. O. Box 302-739
North Harbour
Auckland 0751
New Zealand
PHONE: (+64) 9-476-8500
E-mail: Philip.Thornton@drugs.com

Each Party shall appoint a representative who shall act as the liaisons between such party and the other party's representative. A party may update its representative upon written notice to the other party.

VII. LENGTH OF THE AGREEMENT AND ASSESSMENT MECHANISMS

This MOU will be effective for three years from the date of signature by the later Party to sign it. At the end of each year, and annually thereafter, as long as the Agreement remains in force, the Parties will evaluate the effectiveness of the Agreement in meeting their goals and may amend the Agreement, continue it as written, or dissolve the Agreement by mutual consent. In addition, at any time, the Parties may modify or terminate the Agreement by mutual written consent, and either Party may terminate the Agreement at any time by means of a written notice of termination.

At least every two months, Drugs.com will provide gratuitously, and with no expectation of reimbursement, statistical information to FDA concerning the reach of the cooperative educational program. This information will include metrics on the number of users visiting the joint online resource and individual content items contained therein, as well information concerning the reach of the content integrated with Drugs.com's mobile platform. The Parties agree that Drugs.com will provide information regarding usage to the FDA. This information will be jointly reviewed. The purpose of reviewing this

information will be to evaluate the effectiveness of the collaboration and to make any necessary adjustments in approach, which may include termination of the partnership.

VIII. NO COMMITMENT OF FUNDS

Nothing in this MOU shall be construed to obligate either party to make payments to the other.

IX. LIMITATIONS ON LIABILITY

IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER ANY THEORY OF LIABILITY, HOWEVER ARISING, FOR ANY COSTS OF COVER OR FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF THIS AGREEMENT.

The provisions of this Section IX shall survive termination, cancellation or expiration of this MOU or any reason whatsoever.

X. SIGNATURES OF RESPONSIBLE PARTIES

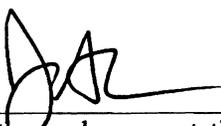
By signing this agreement, the responsible parties agree to the terms and conditions of this MOU, and they further agree to adhere to FDA's policy statement on co-branding of FDA Consumer Health Information.

DRUGS.COM

BY:  10/13/09
Signature of authorized representative Date

PHILIP THORNTON
Chief Executive Officer
Drugs.com

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY:  7/29/09
Signature of authorized representative Date

JOSHUA M. SHARFSTEIN, M.D.
Principal Deputy Commissioner of Food and Drugs
Department of Health and Human Services

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Aviation Security Customer Satisfaction Performance Measurement Passenger Survey

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), OMB control number 1652-0013, abstracted below to the Office of Management and Budget (OMB) for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on March 11, 2010. 75 FR 11552. The collection involves surveying travelers to measure customer satisfaction of aviation security in an effort to more efficiently manage airport performance.

DATES: Send your comments by June 25, 2010. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Joanna Johnson, TSA Paperwork Reduction Act (PRA) Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011; telephone (571) 227-3651; e-mail TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is

available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

OMB Control Number 1652-0013; Aviation Security Customer Satisfaction Performance Measurement Passenger Survey. TSA, with OMB's approval, has conducted surveys of passengers and now seeks approval to continue this effort. TSA plans to conduct passenger surveys at airports nationwide. The surveys will be administered using an intercept methodology. The intercept methodology uses TSA personnel who are not in uniform to hand deliver paper business card style forms that contain a url address to an online survey to passengers immediately following the passenger's experience with the TSA's checkpoint security functions. Passengers are invited, though not required, to view and complete the survey via an online portal. *The intercept methodology randomly selects times and checkpoints to select passengers to complete the survey in an effort to gain survey data representative of all passenger demographics-including passengers who—*

- Travel on weekdays or weekends;
- Those who travel in the morning, mid-day, or evening;
- Those who pass through each of the different security screening locations in the airport;
- Those who are subject to more intensive screening of their baggage or person; and
- Those who experience different volume conditions and wait times as they proceed through the security checkpoints.

The survey includes ten to fifteen questions. Each question promotes a quality response so that TSA can identify areas in need of improvement. All questions concern aspects of the

passenger's security screening experience.

TSA intends to collect this information in order to continue to assess customer satisfaction in an effort to more efficiently manage airport performance. In its future surveys, the TSA wishes to obtain more detailed, airport-specific data that the TSA can use to enhance customer experiences and airport performances. In order to gain more detailed information regarding customer experiences, the TSA is submitting eighty-one questions to OMB for approval. Twenty-eight of the questions have been previously approved by OMB and fifty-three questions are being submitted to the OMB for first-time approval. *Each survey question seeks to gain information regarding one of the following categories:*

- Confidence in Personnel.
- Confidence in Screening Equipment.
- Confidence in Security Procedures.
- Convenience of Divesting.
- Experience at Checkpoint.
- Satisfaction with Wait Time.
- Separation from Belongings.
- Separation from Others in Party.
- Stress Level.

Once a time and checkpoint is randomly selected, TSA personnel distribute forms to passengers until the TSA obtains the desired sample size. The samples can be selected with one randomly selected time and location or span multiple times and locations. Each airport uses a business card that directs customers to an online portal. All responses are voluntary and there is no burden on passengers who choose not to respond.

All airports have the capability to conduct this survey. Based on prior survey data and research, a sample size of 384 needs approximately 1,000 surveys. TSA assumes that there will be 384 respondents from 1,000 surveys distributed. At an individual airport, we assume the burden on passengers who choose to respond to be approximately five-minutes per respondent. Therefore, 384 respondents x 1 airport = 384 respondents a year. It takes approximately 5 minutes for each respondent to complete the survey so the total burden at one airport is 384 respondents x 5 minutes = 1,920 minutes or 32 hours per airport. We estimate that 25 airports will conduct the survey each year. Therefore, 384 respondents x 25 airports = 9,600 respondents a year. Since we assume it takes approximately 5 minutes for each