Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or 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. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

**FOR FURTHER INFORMATION CONTACT:** Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or

David Cummings, Center for Drug Evaluation and Research (HFD–354), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 21, rm. 3525, Silver Spring, MD 20993, 301–796–2400.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics'' dated November 2008. The guidance document provides information concerning the various cooperative manufacturing arrangements used in the production of biological products subject to licensure under section 351 of the PHS Act (42 U.S.C. 262). The guidance describes FDA's current thinking on licensing strategies for meeting the increased need for planning flexible manufacturing arrangements. Because cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance may also be useful for planning purposes in the early phases of product development. Several types of manufacturing arrangements discussed in the guidance include short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements. The guidance supersedes ''FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics'' published in the **Federal Register** of November 25, 1992 (57 FR 55544).

In the **Federal Register** of August 3, 1999 (64 FR 42136), FDA announced the availability of the draft guidance of the same title dated August 1999. FDA received several comments on the draft guidance; those comments were considered as the guidance was finalized. In response to public comments, we clarified the document and reformatted it into plain language. In the **Federal Register** of July 23, 2007 (72 FR 40157), FDA published a 60-day notice requesting public comment on the information collections in the draft guidance of the same title dated July 2007, which revised the draft guidance dated August 1999. The guidance announced in this notice finalizes the draft guidance dated July 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0629.

## III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: November 24, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–28693 Filed 12–3–08; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–N–0043]**
**[FDA No. 225–08–8006]**

### Memorandum of Understanding Between the Food and Drug Administration and WebMD, LLC

**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's Office of External Relations and WebMD, LLC. 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.

Specific elements of the MOU include the creation of an FDA/WebMD online resource on the WebMD.com site, which will feature editorial and visual FDA Consumer Health Information, and the inclusion of FDA Consumer Health Information in at least three issues per year of *WebMD The Magazine*.

An agency policy statement summarizing the criteria and processes for development of this type of collaboration is available on FDA's Web site at *www.fda.gov/consumer/co_brandpolicy.html*.

**DATES:** The agreement became effective October 10, 2008.

**FOR FURTHER INFORMATION CONTACT:** Jason Brodsky, Director, Consumer Health Information Staff, Office of External Relations (HFI–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6251

Nan Forte, Executive Vice President,

WebMD, LLC, 111 8th Ave., 7th floor, New York, NY 10011, 212–624–3821

**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: November 18, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

**BILLING CODE 4160–01–S**

DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA Record No. 225-08-8006

Food and Drug Administration
Rockville MD 20857

**MEMORANDUM OF UNDERSTANDING**
**between**
**THE FOOD AND DRUG ADMINISTRATION**
**and**
**WEBMD, LLC**

## 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 WebMD, LLC.

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 130,000 page views per month. WebMD.com has more than 40 million unique users in a 30-day period. *WebMD the Magazine* is published six times per year and each issue reaches more than 7.8 million health-conscious consumers.

This non-exclusive agreement is consistent with FDA's guiding principles on leveraging practices, which are available online at http://www.fda.gov/oc/leveraging/principles.htm. This MOU also meets the requirements set forth in FDA's policy statement on co-branding of FDA Consumer Health Information, which is available online at www.fda.gov/consumer/cobrand_policy.html.

FDA and WebMD 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 WebMD.

## 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 and safety alerts and WebMD's ability to amplify Web-based dialogue amongst consumers on public health topics. The specifics elements of the Program will include:

- An FDA/WebMD online resource on the WebMD.com site (the "Program"), which will feature editorial and visual FDA Consumer Health Information. The parties will mutually agree to the type and exact items of content made available through the Program and on other parts of the Site. 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.

- Boxed and clearly identified FDA Consumer Health Information, either complementing a story or standing alone, in at least three issues per year of *WebMD The Magazine*. All published content will include the tagline, "Published as part of a U.S. Food and Drug Administration and WebMD partnership to promote public health" or another mutually agreed to tagline.

## 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 WebMD 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 and adhere to published FDA logo policies (see http://www.fda.gov/graphics/FDAlogos1999/).

6. Both parties agree that information FDA provides to WebMD 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. WebMD 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. WebMD'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 WebMD will provide inbound and outbound links on FDA Consumer Health Information materials to and from the individual piece of content as well as the Program. Links to FDA Consumer Health Information Web site and the Program may also appear on other WebMD Web pages and sites, including but not limited to: Medscape, MedicineNet, eMedicine Health, RxList, and www.theheart.Org, as determined by WebMD.

FDA will not provide WebMD 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

Nan Forte
Executive Vice President
WebMD, LLC
111 8th Avenue 7th Floor
New York, NY 10011
PHONE: 212-624-3821
E-mail: nforte@webmd.net

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. ASSESSMENT MECHANISMS**

This MOU will be effective for one year from the date of signature by the later Party to sign it. At the end of that 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, WebMD will provide gratuitously, and with no expectation of reimbursement, FDA statistical information concerning the number of users visiting the FDA/WebMD joint online resource and individual content items contained therein. The Parties agree that WebMD will provide information regarding usage of the Program 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.

FDA Record No. 225-08-8006

**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.

APPROVED AND ACCEPTED FOR WebMD, LLC

By: Eric A. Abelow
ERIC S ABELOW

Title: SVP Business Partner Development

Date: October 1, 2008

APPROVED AND ACCEPTED FOR THE FOOD & DRUG ADMINISTRATION

By: Susan C Winckler
Susan C. Winckler

Title: Chief of Staff

Date: October 10 2008

[FR Doc. E8–28690 Filed 12–3–08; 8:45 am]

BILLING CODE 4160–01–C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(cX4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflicts: Musculoskeletal Rehabilitation Sciences.

*Date:* December 9, 2008.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, *holdenjo@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 25, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–28622 Filed 12–3–08; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Services Subcommittee of the Interagency Autism Coordinating Committee (IACC).

The purpose of the Services Subcommittee is to review the current state of services and supports for individuals with Autism Spectrum Disorder (ASD) and their families in order to improve these services. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 5 business days in advance of the meeting. The Subcommittee will report on its meeting at the February meeting of the IACC.

*Name of Committee:* Interagency Autism Coordinating Committee (IACC).

*Type of meeting:* Services Subcommittee.

*Date:* December 10, 2008.

*Time:* 2 p.m. to 5:30 p.m. Eastern Time.

*Agenda:* To review public comments received in response to a completed Request for Information from Autism Spectrum Disorders (ASD) stakeholders about what they consider to be high-priority issues and concerns surrounding services and supports for children, youth, and adults with ASD.

*Place:*

In Person: National Institutes of Health, 9000 Rockville Pike, Building 31C, Conference Room 7,Bethesda, MD 20892.

Webinar: *https://www1.gotomeeting.com/register/563207085*. To Access the Conference Call: Dial: 888–455–2920, Access code: 3857872.

*Contact Person:* Ms. Lina Perez, Office of Autism Research Coordination, Office of the Director, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 8204a, Bethesda, MD 20892–9669, 301–443–6040, *IACCPublicInquiries@mail.nih.gov*.

**Please Note:** The meeting will be open to the public with limited seating. In addition, the public can access the meeting through a conference call phone number and a Web presentation tool on the Internet. Individuals who participate using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request at least 5 days prior to the meeting.

Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. There may be an opportunity for members of the public to submit written comments during the Subcommittee meeting through the Web presentation tool. Submitted comments will be reviewed after the meeting. If you experience any technical problems with the Web presentation tool, please contact GoToWebinar at (800) 263–6317.

To access the Web presentation tool on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

This notice is being published less than 15 days prior to the meeting due to the urgency to review the public comments received in response to a completed Request for Information from Autism Spectrum Disorders stakeholders.

Information about the IACC is available on the Web site: *http://www.iacc.hhs.gov*.

Dated: November 26, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–28743 Filed 12–3–08; 8:45 am]

BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, December 9, 2008, 8:30 a.m. to 3:55 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on November 24, 2008 73 FR 71015.

This notice is amended to change the start time of the open session on December 9, 2008 to approximately 11:15 a.m. and the end time to 3:30 p.m. The closed session will be held from 3:30 p.m. to 3:55 p.m.

Dated: November 25, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8–28727 Filed 12–3–08; 8:45 am]

BILLING CODE 4140–01–P