This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27693 Filed 11–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

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 notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, NIH.

Date: December 4, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: Among the topics proposed for discussion are: (1) NIH Director's Report; (2) NIH Director's Council of Public Representatives Liaison Report; and (3) other business of the Committee.

Place: National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20852.

Contact Person: Penny W. Burgoon, PhD, Senior Assistant to the Deputy Director, Office of the Director, National Institutes of Health, 1 Center Drive, Building 1, Room 109, Bethesda, MD 20892, 301–451–5870, *burgoonp@od.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nih.gov/aboutldirector/acd.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 5, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27411 Filed 11–17–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0667]
[FDA 225–09–0013]

Memorandum of Understanding Between the Food and Drug Administration and Waterfront Media

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 Waterfront Media. 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 October 14, 2009.

FOR FURTHER INFORMATION CONTACT: Jason Brodsky, Consumer Health Information Staff, Office of External Relations (HFI–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6251, 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: November 12, 2009.

David Horowitz,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MOU Number: 225-09-0013

MEMORANDUM OF UNDERSTANDING
between
THE FOOD AND DRUG ADMINISTRATION
and
WATERFRONT MEDIA

I. PURPOSE, GOALS AND DEFINITIONS

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 Waterfront Media Inc., the operator of the Everyday Health Network of health, diet and fitness websites ("Everyday Health").

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 emerging safety issues and product recalls.

The "**Program**" means a public health education program intended to provide practical wellness and prevention tips and the latest safety information on websites, mobile websites and other electronic means of distribution (including electronic newsletters) but solely to the extent that the FDA Materials are agreed upon by the parties (as provided in Section IV) and delivered to the public under the brands of the FDA and Everyday Health (as provided in Section III, co-branding). The Program includes promotional modules and banners used by Everyday Health to drive traffic to the Program Pages.

"**Program Pages**" mean electronic newsletters and any web pages that contain FDA and Everyday Health co-branding in the header. For the avoidance of doubt, the parties state that the following are specifically excluded from the definition of Program Pages: any page on which the only FDA Materials are promotional modules that contain an FDA logo.

The "**Everyday Health Network**" means each and every website that is publicly designated by Everyday Health as a member of the Everyday Health network, a portfolio of health, wellness, diet, fitness and pregnancy websites targeted to consumers. For the purposes of this Agreement only, the sites listed in Exhibit A shall not be considered part of the Everyday Health Network.

"**FDA Materials**" mean the audio and video files, photos or other editorial materials provided by FDA for publication as part of the Program.

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 located at the URL www.fda.gov 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. Waterfront Media is the largest privately held online health company and operates The Everyday Health Network, which attracts, as of the Effective Date, over 20 million unique users per month across 24 sites, generates 300 million monthly page views and delivers more than 15 million electronic newsletters daily.

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 http://www.fda.gov/ForConsumers/ucm126390.htm.

FDA and Waterfront Media recognize that this 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 Everyday Health.

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 to engage the public. The cooperative public education program will include the following components:

- An FDA/Everyday Health joint online resource on the EverydayHealth.com site which will feature FDA Consumer Health Information including but not limited to articles, videos, photo slideshows and other editorial material. Except as provided in Editorial Control Section below regarding Direct from the FDA Alert modules, the parties will mutually agree to the type and exact items of content made available through the Program Pages. As a general matter, it is the current expectation of the parties that the Program will feature a minimum of 50 articles of FDA content and provide users with access to the agency's catalog of Consumer Updates. Each Program Page will include a link to a tagline to be agreed upon by the parties, that describes the relationship between the FDA and Everyday Health. For example, and for illustration purposes only, "This special section is published by Everyday Health in coordination with the U.S. Food and Drug Administration as part of a public health education program. Unless otherwise indicated, the content is created by the FDA and selected for publication by the Everyday Health editorial team. The FDA content is not edited by Everyday Health and is under the sole editorial control of the FDA. Content labeled DIRECT FROM THE FDA is both created and selected by the FDA without modification by Everyday Health."

- An FDA/Everyday Health co-branded weekly newsletter which will point to the latest FDA Consumer Health Information on Program Pages. Everyday Health will manage the newsletter subscriber list, creation and delivery of the co-branded newsletter. Each issue of the newsletter will include a tagline to be agreed upon by the parties, that describes the relationship between the FDA and Everyday Health. For example, and for illustration purposes only, "This newsletter is published by Everyday Health in coordination with the U.S. Food and Drug Administration as part of a public health education program. Unless otherwise indicated, the content in this newsletter is created by the FDA and selected for publication by the Everyday Health editorial team. The FDA content is not edited by Everyday Health and is under the sole editorial control of the FDA. Content labeled DIRECT FROM THE FDA is both created and selected by the FDA without modification by Everyday Health."

- In addition, FDA and Everyday Health will work together to extend the reach of FDA Consumer Health Information and to engage the public within the Everyday Health online community. A process for implementing community activities is to be mutually developed and agreed to by both parties.

- Editorial Control. Standard Process. It is the intent of the Parties that the Program will operate as follows: (a) the FDA will provide the FDA Materials to Everyday Health in a format and schedule to be agreed upon by the parties; (b) Everyday Health may, at its discretion, publish or not publish the FDA Materials within the Program after consultation with the FDA as part of a periodic editorial meeting; and (c) when Everyday Health publishes the FDA Materials, it will do so without editing the FDA Materials and will display the FDA Materials in conformance with the co-branding requirements set forth in Section III. Special Process. In the event that Everyday Health elects not to publish certain FDA Materials that the FDA believes are Critical to disseminate to the public, Everyday Health will publish such FDA Materials in a standard size module on the Program landing page. This special process will occur no more than eight times per month; the FDA Materials will consist of teasers that link back to the FDA Website and will meet the technical specifications agreed upon by the parties (e.g., character limitations). "Critical" means issues related to major product recalls or withdrawals, safety issues, a public health emergency/crisis or a major new policy initiative or regulation affecting consumers.

- The parties will make good faith efforts to ensure that the Program is consumer friendly and designed to maximize search engine optimization. The design, look and feel of the Program Pages was developed by Everyday Health and agreed to by the FDA prior to publishing as provided in the Review bullet below.

- Promotion. Everyday Health will promote the Program Pages and newsletter registrations on the Everyday Health Network through the use of banners and modules (both alert and promotional).

- Review. The parties have created and completed a process whereby the FDA has reviewed and approved all Program components, activities and program publishing templates (including landing pages, article pages, newsletters and modules). For the avoidance of doubt, the parties state that such review has included approval of the program pages publishing template for compliance with Section 508 (see Section V (5) below). Everyday Health will publish the Program Pages using only the approved templates in conformance with the process described in the Editorial Control section above. In the event that FDA reviews any Program Page on a post-publication basis and determines that any of the FDA Materials need to corrected or removed, FDA can request changes as provided in Section V(7).

- Everyday Health E-mail Alerts are not part of the Program, but may link back to Program Pages. The parties acknowledge that, based upon the FDA Materials, Everyday Health may deliver email alerts that inform the public of significant public health issues involving food, drug and medical product safety (e.g., major product recalls and public health emergencies). These alerts will be branded with Everyday Health logos and it will be clear to users that any alert is being sent by Everyday Health without association with the FDA (see Section V(1) below). These email alerts may, however, link to Program Pages.

V. TERMS OF THE MOU

1. FDA Materials must be easily distinguishable from non-FDA content within the Program. FDA Materials within the Program should be clearly identified as such. Examples of clearly identifying FDA Materials 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. FDA Materials that are selected entirely by the FDA and published in modules labeled Direct from the FDA will be distinguished further from the FDA Materials selected by Everyday Health.

3. Printed and online Program Pages (including newsletters) must be free of advertisements to avoid implying FDA's endorsement or support for a particular product, service or Web site. For the avoidance of doubt, the parties state that any page which is not a Program Page may contain advertisements.

4. 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.

5. 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). The parties will cooperate in ensuring compliance with Section 508. All FDA Materials will be provided by the FDA in a manner that is Section 508 ready (e.g., video and audio files will be supplied with closed captions).

6. FDA and Everyday Health will cooperate in the maintenance of each party's trademarks and logos. Neither party will permit use of its logo for marketing purposes other than to promote the Program. The use of the other party's names or logos shall not imply any exclusive arrangement. Any use of the other party's logos must be approved, in advance, by the trademark owner. Use of FDA's logo must be approved in advance by the FDA's Consumer Health Information Staff.

7. Both parties agree that the FDA Materials shall be public domain material. FDA shall have full rights to reuse the FDA Materials for all FDA purposes, and the right to share with other collaborators or requestors. Any materials created by Everyday Health based on the FDA Materials will be owned exclusively by Everyday Health. Nothing in this Agreement will prohibit Everyday Health from writing about the FDA or its activities on any page that is not a Program Page and any such writing will not be subject to the approval or review of the FDA.

8. Everyday Health will maintain current FDA Materials within the Program Pages. FDA Materials must be removed from the Program Pages in the following circumstances: (1) within 3 years of the date of its first publication; (2) upon FDA's request in circumstances in which the information becomes outdated; or (3) as soon as commercially practicable after a written request from the FDA for any reason with the expectation that the requested material will be removed within 72 hours after receipt of a written request from FDA, regardless of reason. Everyday Health's failure to display current FDA Consumer Health Information may result in the termination of this Agreement. In addition, no more than once each quarter, Everyday Health will adhere to any written FDA request to revise FDA Materials published within the Program Pages to the extent that FDA believes such information is now incorrect, inaccurate or misleading. Everyday Health will use reasonable commercial efforts to comply with FDA requests for modifications within five business days.

9. Except for the limited permission to use content and logos discussed herein, this Agreement does not and is not intended to transfer to either party any rights in any technology or intellectual property.

V. LINKS

The FDA website will contain links that transport visitors to the Program landing page. It is the intent of the parties that the links from the co-branded newsletters and modules will link to Program Pages. At its discretion, Everyday Health may link directly to relevant information on the FDA website.

FDA will not provide Everyday Health access to any document or information to the extent that providing such access would place either party 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
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Kathleen Healy
Vice President, Content Development
Waterfront Media
Suite 600
1250 Connecticut Avenue, NW
Washington, D.C. 20036
PHONE: 202-481-6749
E-mail: khealy@waterfrontmedia.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. Either party may terminate the MOU with no less than thirty (30) days notice. Upon termination of this MOU for any reason, Everyday Health will remove the Program Pages and all modules with FDA logos from the Site as soon practicable, but in no event later than thirty (30) from the date of any notice of termination. For the avoidance of doubt, the parties state that this paragraph is intended to address use of the FDA Materials on Program Pages and is not intended to alter Everyday Health's rights to use public domain FDA Materials on any website, mobile website or other medium except for Program Pages.

Waterfront Media will provide gratuitously, and with no expectation of reimbursement, statistical information concerning the reach of the cooperative educational program's components and activities to FDA. This information will include metrics on the number of unique visitors to the Program Pages, the

total number of Program Pages viewed and other metrics agreed upon by the parties. 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 MOU.

VIII. NO COMMITMENT OF FUNDS

This MOU sets forth principles and guidelines by which the parties intend to engage in a cooperative public education program. Nothing in this MOU shall be construed to obligate either party to make payments to the other. Each party will be responsible for the costs of its performance hereunder.

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 DIRECT, 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 for 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.

WATERFRONT MEDIA INC.

BY: _____ 10/14/09
Signature of authorized representative Date

BENJAMIN WOLIN
Co-Founder and CEO
Waterfront Media Inc.

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 9/22/9
Signature of authorized representative Date

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

Exhibit A

Drugstore.com

[FR Doc. E9–27630 Filed 11–17–09; 8:45 am]
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