thus, the critical path pipeline. This research does not require clinical or animal studies. Instead, it will lead to the creation of materials with physical properties in materials that have been previously identified as being desirable.

- Physical characteristics of active ingredients and recipients in drug products, such as crystal morphology, co-crystal technology, dispersions, and particle sizing including nanotechnology are not fully developed in the public sector. This work will develop technology enabling control of these attributes. This will provide another dimension of control to the predictability of pharmaceutical products. This added control will enable new approaches to manufacturing novel dosage forms and shorten the time it takes to develop manufacturing processes and controls.
- Development of specialized manufacturing techniques suitable for products administered in low dosages and for products with high toxicity or narrow therapeutic ranges. This will enable more rapid development of manufacturing techniques for these products.
- Development of models for manufacturing and engineering of device products such as infusion pumps, prosthetic organs, defibrillators, tissue engineering devices, and combination products will help standardize the approach for bringing these medical products to market. This includes development of components for more reliable delivery of pharmaceuticals to the most desirable site of action, for example, controlling the air plume of inhaled products. This will shorten the time required to move such products from concept to patient and thereby shorten the Industrialization sector of the Critical Path.
- Research into methods for laboratory synthesis of molecules that have been designed by computer simulation will shorten medical product development time. These methods will make the creation of these molecules more predictable. These technologies will also enable new drug discoveries to be brought to market faster with less variability; higher predictability of performance.
- Approaches to improve facilities where this research will be conducted. Advanced technology development can be accelerated by better design of the facilities where this research is conducted. Creating and making these designs public will have the effect of accelerating technology across the industry. This will shorten the time it takes to bring these advanced technologies into the product manufacturing sector.

C. Eligibility Information

National Institute for Pharmaceutical Technology and Education Initiative (NIPTE), a Nonprofit Other Than Institutions of Higher Education, described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3), which is exempt from tax under section 501(a) of that code.

NIPTE is the only consortium of universities of its kind. The organization consists of many of the most highly qualified pharmaceutical manufacturing experts in academia. Research conducted by NIPTE Faculty is collaborative by design to provide for coordinated publication of the cutting-edge research results.

An eligible organization that wishes to enter into a collaborative agreement must provide an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership Project from any organization that manufactures or distributes products regulated by FDA unless the entity provides assurance in its agreement with FDA that the results of the Critical Path Public Partnership project will not be influenced by any source of funding. The entities eligible to enter into partnerships with FDA are governed by section 566 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb5).

This cooperative agreement will provide continued support for established and previously funded collaborations on behalf of FDA priorities.

II. Award Information/Funds Available

A. Award Amount

Only one grant will be awarded. In fiscal year 2011, there is currently $700,000 available. As funds are available, partner components may supplement up to $7,000,000 total cost per year, depending on the availability of fiscal year funds.

B. Length of Support

Application budgets are not limited, but need to reflect actual needs of the proposed project. This Cooperative Agreement is capable of awarding a total of $35,000,000 over the entire award project period depending upon progress, the need for, and the availability of fiscal year funds.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/About FDA/CentersOffices/CDER/ucm088761.htm* located under the ''Regulatory Information'' section. The title of the page is ''Research Acquisitions.''

Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/forms.htm.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons.

Steps 1 and 2, in detail, can be found at: *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to Gladys Melendez, Grants Management Officer/Grants Management Specialist (see *For Further Information and Additional Requirements Contact*).

Dated: July 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17515 Filed 7–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0005]

Memorandum of Understanding Between the Food and Drug Administration and MEDSCAPE, LLC 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 and MEDSCAPE, LLC AND WEBMD LLC. The purpose of the MOU is to complement FDA's capacity to educate and communicate with health care professionals. It will also promote the timely dissemination to health care professionals of accurate information on public health and emerging safety issues and products safety recalls.

DATES: The agreement became effective June 8, 2011.

FOR FURTHER INFORMATION CONTACT:

Anna Fine, Office of Special Health Issues, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5337, Silver Spring, MD 20993–0002, 301–796–8471, e-mail: *Anna.Wojas@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: July 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

MEMORANDUM OF UNDERSTANDING
BETWEEN
U.S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
MEDSCAPE, LLC AND WEBMD LLC (each a "Party" and collectively the "Parties")

I. Purpose

This Memorandum of Understanding (MOU) defines the framework in which the Food and Drug Administration (FDA) will provide publicly available content to be used in health professional informational, educational, and training programs that will be run by WebMD LLC ("WebMD") and Medscape, LLC ("Medscape"), an entity accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Nurses Credentialing Center (ANCC) and the Accreditation Council for Pharmacy Education (ACPE) to provide continuing professional education to physicians, nurses and pharmacists, respectively. These programs will provide information, education and training for physicians, nurses, pharmacists, and health professionals (collectively referred to herein as "HCP's") on medical product safety and efficacy issues and, in certain cases, will offer HCP's the opportunity to obtain continuing medical education (physicians) and continuing education (nursing, pharmacy) credit (collectively, "CME") in connection with such programs. This collaboration will complement FDA's capacity to educate and communicate with HCP's. It will also promote the timely dissemination to HCP's of accurate information on public health and emerging safety issues and product safety recalls.

II. Background

The FDA is responsible for protecting the public health by assuring that foods are safe, wholesome, sanitary, and properly labeled; biologics for human use and human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of medical devices intended for human use; cosmetics are safe and properly labeled; public health and safety are protected from electronic product radiation; and tobacco products are labeled and marketed in accordance with applicable statutes and regulations.

The FDA is also responsible for advancing the public health. FDA helps to speed innovations that make medicines and medical devices more effective, safer, and more affordable; and helps the public get the accurate, science-based information they need to use FDA-regulated products to improve their health ("FDA Health Information").

Through their respective online portals and mobile applications (collectively, the "WebMD Health Professional Network"), Medscape and WebMD offer HCP's a

variety of information resources and communications services including, but not limited to, peer-reviewed original medical journal articles, CME, a customized version of the National Library of Medicine's MEDLINE database, daily medical news, major conference coverage, and drug information—including a drug database (Medscape Drug Reference, or MDR) and drug interaction checker and Medscape Physician Connect, a physician-only social network.

III. Authority

FDA has authority to provide information to the public pursuant to section 705(b) and section 903(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 375(b) and 393(d)(2)(D).

IV. Substance of Understanding

FDA will work with Medscape and WebMD, as applicable depending on the nature of the services being developed, to define approaches for web links, the delivery and sharing of content, and CME program assessment, development and delivery protocols in order to facilitate the dissemination of FDA Health Information. As part of this effort, FDA and Medscape will identify FDA public health and product alerts, guidance, service descriptions and educational programs for HCP's.

V. General Provisions

A. This MOU does not grant exclusivity to either Party, nor does it restrict FDA, Medscape or WebMD from participating in similar initiatives with other public or private agencies, organizations or individuals.

B. FDA Health Information must be easily distinguishable from non-FDA content on Medscape and WebMD web pages. FDA Health Information placed on Medscape and WebMD web pages should be clearly identified as such.

C. Printed and online web pages containing FDA Health Information provided by FDA pursuant to this MOU must be free of advertisements, and otherwise must avoid implying FDA's endorsement or support for a particular product, service or website.

D. FDA, Medscape and WebMD recognize that this MOU is not intended to, 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, Medscape or WebMD.

E. All materials and programming produced pursuant to this collaboration must be accessible by and free of cost to the general public.

F. All activities within the scope of this MOU must comply with section 508 of the Rehabilitation Act (29 U.S.C. § 794d), as amended by the Workforce Investment Act of 1998, Pub. L. No. 105-220, Aug. 7, 1998 (see U.S. Department of Health and Human Services policy on section 508 compliance at http://www.hhs.gov/od/508policy/index/html; and Office of Management and Budget policies for protecting private information at www.usa.gov/webcontent/reqs_bestpractices/laws_regs/privacy/shtml).

G. Both parties agree that content provided to Medscape or WebMD by FDA in connection with the collaboration shall be public domain material and as such, FDA shall have full rights to reuse such content for all FDA purposes and the right to share with other collaborators or requestors.

H. Medscape and WebMD agree to maintain current FDA Health Information within their web pages. FDA Health Information must be removed from Medscape and WebMD websites in the following circumstances: (1) within three years of the date of its first publication, unless an extension of a definite term is agreed to by FDA in advance of expiration of the three-year period; (2) upon termination of this MOU, if the MOU terminates less than three years after the material is posted; (3) upon FDA's request in circumstances in which the information becomes outdated; or (4) as soon as is commercially practicable but no longer than 72 hours after receipt of FDA's written request to remove the material, regardless of reason. Medscape or WebMD's failure to display current information or to remove information in accordance with this MOU may result in termination of this MOU and related activities.

I. FDA retains the right to review all materials produced through this collaboration prior to WebMD's or Medscape's public distribution or posting of such materials, and the right to prohibit the public distribution or posting of such materials.

J. Medscape and WebMD will include the following disclaimer language in a clearly distinguishable manner on any web pages on which FDA Health Information provided by FDA pursuant to this MOU is placed: "Information provided by FDA and/or its employees on this website is for educational purposes only, and does not constitute medical advice. Any statement or advice given by an FDA employee on this website does not represent the formal position of FDA. FDA and/or any FDA employee will not be liable for injury or other damages resulting to any individuals who view FDA-related materials on this website." FDA reserves the right to modify this disclaimer language.

K. FDA and Medscape and WebMD will cooperate in the maintenance of each party's trademarks and logos. Medscape and WebMD agree that they will not use FDA's logo for marketing purposes other than to promote activities

engaged in pursuant to this agreement. The use of FDA names and logos shall not imply any exclusive arrangement. Any use of FDA logos must be approved, in advance, by FDA's Office of Special Health Issues and adhere to published FDA logo policies (see http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ucm218116.htm).

L. This MOU does not and is not intended to transfer to any Party any rights in any technology or intellectual property of any other Party hereto, other than Medscape's ability to display the FDA logo subject to the restrictions specified under Paragraph J above. For avoidance of doubt, any intellectual property including, without limitation, content, products, technology, data and other information, provided by Medscape or WebMD for use in the collaboration shall in all cases remain solely owned by Medscape or WebMD, as applicable, and no license to use such information is granted under this MOU.

M. FDA and Medscape and/or WebMD may in the future engage in activities relating to certain funded activities. Those activities are entirely independent of this MOU and shall in no respect be subject to any term of this MOU.

N. Except as required by law or regulation, including but not limited to publication of this MOU and related materials in the Federal Register, neither party will make any public announcement (including press releases) about this MOU or the subject matter thereof without first obtaining the other party's prior written approval of such announcement.

VI. Resource Obligations:

All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. Medscape and WebMD are not being compensated by FDA for the activities conducted under the MOU, and funds are not otherwise being obligated under the MOU. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA, Medscape and WebMD operate.

VII. CONTACT POINTS

A. Food and Drug Administration

Anna Fine
Office of Special Health Issues
Office of External Affairs
U.S. Food and Drug Administration
301-796-8471
Anna.wojas@fda.hhs.gov

B. Medscape, LLC or WebMD LLC

Amy Nadel
825 Eighth Avenue, 11th Floor
New York, NY 10019
212-301-6727
anadel@medscape.net

VIII. LIMITATIONS ON LIABILITY

In no event will any party hereto be liable to the other under any theory of liability, however arising, for any costs or cover or for indirect, special, incidental, or consequential damages of any kind arising out of this MOU. The provision shall survive termination, cancellation or expiration of this MOU or any reason whatsoever.

IX. Term, Termination, and Modification:

This MOU, when accepted by all Parties, will have an effective period of performance from the date of the latest signature until three years and may be modified or terminated by mutual written consent by both Parties. Any party may terminate the agreement at any time, but such Party should provide 60-day advance written notice to the other Parties of such termination.

By signing below, the Parties accept the conditions that accurately represent the understanding reached between them.

FOOD AND DRUG ADMINISTRATION

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Date: 6/8/11

Medscape, LLC

Ezra T. Ernst
Senior Vice-President, General Manager

Date: 5-19-11

WebMD LLC

Steve Zatz, MD
Executive Vice-President
WebMD Health Corp.

Date: 05/19/11

[FR Doc. 2011–17565 Filed 7–12–11; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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(c)(4) 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 Commitee: National Institute of General Medical Sciences Special Emphasis Panel, K99 Pathway to Independence Grant Applications Review.

Date: August 2, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: John J. Laffan, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18J, Bethesda, MD