

approval expires on June 13, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0012]

Critical Path Manufacturing Sector Research Initiative (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a cooperative agreement with the National Institute for Pharmaceutical Technology and Education Initiative (NIPTE).

Development of the Critical Path Manufacturing Sector Initiative has focused attention on the continuing need for this kind of research in a way that can improve reliability of pharmaceutical product manufacturing and quality across the entire industry. This shared knowledge will increase the likelihood of successfully manufacturing products that have been identified in the clinical development community. The goal of this agreement is to improve the overall manufacturing and quality and the knowledge base.

DATES: Important dates are as follows:

1. The application due date is July 20, 2011.
2. The anticipated start date is August 31, 2011.
3. The opening date is July 13, 2011.
4. The expiration date is July 22, 2011.

For Further Information and Additional Requirements Contact:

For Programmatic and Scientific Questions and Concerns contact:

Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4178, Silver Spring, MD 20993, 301-796-2400; E-mail: Jon.Clark@fda.hhs.gov.

For Administrative and Financial Questions and Concerns contact: Gladys Melendez, Office of Acquisitions and Grant Support, Food and Drug

Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175; E-mail: gmb@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm088761.htm> under the "Regulatory Information" section. The title of the page is "Research Acquisitions."

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA-FD-11-014.

Catalog of Federal Domestic Assistance: 93.103.

A. Background

The Office of Pharmaceutical Science has conducted research within the academic community through contracts in order to improve the overall manufacturing and quality knowledge base. This research is important to the public sector, because research conducted in pharmaceutical sciences related to product quality is typically kept proprietary.

Development of the Critical Path Manufacturing Sector Initiative has focused attention on the continuing need for this kind of research in a way that can improve reliability of pharmaceutical product manufacturing and quality across the entire industry. This shared knowledge will increase the likelihood of successful manufacturing.

B. Research Objectives

The grant will support programs and research as described in the following paragraphs, related to the manufacturing of drugs, biological products, and medical devices:

- Education and training in the field of manufacturing and scale-up, for product development partnerships, academic scientists, other product developers and product application reviewers.
- Development of platform strategies and standardized approaches for medical product manufacturing to shorten timelines for manufacturers to produce quality medical products at commercial scale. This will provide publicly available models for manufacturing and scale-up that will help enable small firms to expeditiously market important treatments.
- Development of analytical methodologies and advanced computational methodologies to better characterize complex molecules and complex mixtures of molecules is needed to better understand and control

manufacturing processes and product quality. Specific analytical techniques will better enable standardized approaches to manufacturing control and advance computational technologies will help to identify atypical samples of complex molecules. These advances will help assure pharmaceutical quality for the American public.

- Research into improved techniques for collection and analysis of process data to control processes and to ensure that they are in statistical control will be done. This includes science-based flexible and adaptive approaches to manufacturing utilizing feed forward and feed backward information flow. Standardized approaches to assuring product quality using manufacturing and analytical data will support continued product quality and lessen manufacturing failures thus decreasing shortages of medically necessary products.

- Development of techniques for assuring product quality using surrogates for desired clinical results will improve understanding of quality target product profile. This approach takes advantage of the potential to use existing clinical data to determine clinically relevant specifications including unit-to-unit variability, drug dissolution, and other material or product attributes, and to support future manufacturing improvements while maintaining product quality.

- Creating simulation models for manufacturing techniques including but not limited to biotech fermentation and cell culture, small molecule crystallization, freeze drying techniques, and precision tablet coating will enhance industry knowledge. These models will enable a more predictable approach to manufacturing development and design of control systems. This predictability will shorten the critical path pipeline from laboratory to clinic and support continual improvement to achieve product quality of the drug's lifecycle.

- Creating simulation models for complex drug delivery devices such as dry product inhalers, transdermal patches, and liposomal products to better understand the product design and performance and to control the critical manufacturing parameters. These models will aid to speed the development of novel dosage forms and decrease the failure rates of these products.

- Research into product formulation for special patient populations or product formulation to ensure chemical stability of active ingredients will shorten formulation development and

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](http://www.fda.gov/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.

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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: