Dated: December 24, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–31142 Filed 1–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0667]
[FDA 225–09–007]

Memorandum of Understanding Between the United States Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research and Northeastern University

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 Northeastern University. The purpose of the MOU is to form a collaborative relationship between FDA and Northeastern University; provide opportunities for exchanging of graduate and undergraduate students, faculty, and personnel and for advanced training and outreach; stimulate cooperative research, and information exchange in biological product characterization and regulation with Northeastern University's Barnett Institute of Chemical and Biological Analysis; and develop training programs for FDA and potentially other Government agencies and Industry in the broad areas of biotechnology and analytical chemistry.

DATES: The agreement became effective November 19, 2009.

FOR FURTHER INFORMATION CONTACT: Keith O. Webber, Office of Pharmaceutical Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–2400, e-mail: *Keith.webber@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: December 17, 2009.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

BILLING CODE 4160–01–S

Control No. 225-09-0007

MEMORANDUM OF UNDERSTANDING
BETWEEN THE
NORTHEASTERN UNIVERSITY
AND THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

I. Preamble:

This Memorandum of Understanding between the U.S. Food and Drug Administration and Northeastern University is established to develop collaboration between the two parties in the areas of education, research, and outreach.

II. Purpose:

The objectives of this collaborative relationship resulting from this MOU include:

1. development of a collaborative working relationship between U.S. Food and Drug Administration and Northeastern University
2. provision of exchange of graduate and undergraduate students, faculty, and personnel, for the purposes of advanced training and outreach,
3. stimulation of cooperative activities, research, and information exchange in areas such as biological product characterization and regulation with Northeastern University's Barnett Institute of Chemical and Biological Analysis
4. development of training programs for U.S. Food and Drug Administration and potentially other Government agencies and Industry in the broad areas of biotechnology and analytical chemistry.

III. Background:

FDA is authorized to enforce the Federal Food, Drug, and Cosmetic Act (the Act) as amended (21 U.S.C. 301). In fulfilling its responsibilities under the Act, FDA among other things, directs its activities toward promoting and protecting the public health by assuring the safety, efficacy, and security of drugs, veterinary products, medical devices and radiological products and the safety and security of foods and cosmetics. To accomplish its mission, FDA must stay abreast of the latest developments in research and also communicate with stakeholders about complex scientific and public health issues. Increased development of research, education and outreach partnerships with Northeastern University will greatly contribute to FDA's mission.

Northeastern University (NU), a private research university located in Boston, MA, is a leader in interdisciplinary, translational research and experiential education. NU has

active research programs in medicinal chemistry, drug targeting, molecular imaging and bioengineering. Educational programs in various areas of biotechnology, including professional science masters and Ph.D. programs are offered. NU's Barnett Institute of Chemical and Biological analysis is an internationally recognized research center in the field of protein and carbohydrate analysis. It has established a Center for Advanced Regulatory Analysis focused in the development and application of new technologies to biopharmaceutical analysis.

IV. Substance of Agreement:

The Memorandum of Understanding is intended as a broad vehicle to promote programmatic interaction in the form of joint collaboration between U.S. Food and Drug Administration and Northeastern University researchers, students, and personnel as well as joint development of relevant projects.

The collaboration may include the following:

Joint exchange program. These exchanges would include internships, research opportunities, and shadowing opportunities for Northeastern University undergraduate, post-baccalaureate and graduate students at the U.S. Food and Drug Administration. Faculty and senior staff from U.S. Food and Drug Administration and Northeastern University and other collaborators will be encouraged to participate in the work of the sister institutions for mutual research and training interactions.

Joint research programs. Joint research programs will be formed by scientists from the respective institutions with mutual complementary interests.

Joint training activities. Training activities arising from complementary interests will be developed by Northeastern University and offered to U.S. Food and Drug Administration, industry, and others as identified needs arise.

Joint dissemination of information and outreach. The partners will disseminate information and enhance the visibility of the work of the collaboration through mutually agreed vehicles including training activities, meetings, and symposia.

Participants will include faculty and students from Northeastern University's Barnett Institute, as well as other relevant departments at Northeastern University. Participants from the U.S. Food and Drug Administration may include scientists from the the Center for Drug Evaluation and Research or other FDA Centers and investigators from the FDA Office of Regulatory Affairs.

V. General Provisions:

- Data Sharing Guidelines: Access to non-public information shall be governed by separate Confidentiality Disclosure Agreements in which the Parties will agree and certify in writing that they shall not further release, publish or disclose such information and that they shall protect such information in accordance with the provisions of 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 18 U.S.C. 1905, and other pertinent laws and regulations governing the confidentiality of such information. No proprietary data, tradesecrets or patient confidential information shall be disclosed among the Parties unless permitted by applicable law.

- Intellectual Property Guidelines: "Invention" refers to any subject matter or discovery patentable under Title 35 of the United States Code and conceived or first reduced to practice under the activities of the MOU. "Intellectual Property" refers to patents, patent applications, know-how, trade secrets, copyrights and computer programs either use or developed under the activities of the MOU. Rights to Inventions or Intellectual Property developed under the MOU will be addressed in separate project-specific development and implementation agreements among the Parties. Inventorship will be governed by U.S. law. In the case of sole inventorship, ownership will be governed by the policies of the employer of the Invention. In the case of joint Inventorship, ownership of Inventions will be jointly owned. Inventions made under a Federal grant or contract will be subject to the Bayh-Dole Act. No Party, by virtue of their participation in activities under the MOU, will be required to disclose or license intellectual property to the other Party.

- Conflict of Interest: Participants in activities under this MOU who are not U.S. Government employees will be expected to abide by conflict of interest rules and policies as specified by FDA. This may require participants to disclose their financial holdings and those of their spouse and minor children, and may limit their ability to accept gifts and have employment with entities that are substantially regulated by FDA. The Parties will be advised of any potential conflict so that conflicting assignments can be avoided consistent with the HHS/FDA requirements. If at any time prior to or during the performance of the activities under the MOU, the Parties believe that a potential or actual conflict exists, the Parties must notify the appropriate authorities within their respective institutions and contact the designated FDA official listed on the MOU so that the necessary action can be undertaken. A determination will be made by FDA as to whether a conflict of interest exists and, if so, as to how to resolve or mitigate it. Parties to the MOU will make every effort to avoid activities or relationships that would cause a reasonable person to question the impartiality of their actions.

VI. Resource Obligations:

This MOU represents the broad outline of the Parties' intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and Northeastern University. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and Northeastern University operate.

VII. Liaison Officers:

A. For the Northeastern University:
Kenneth Blank, Ph.D.
Vice Provost for Research
Northeastern University
360 Huntington Ave.
Boston, Massachusetts 02115

B. For the Food and Drug Administration:
Keith O. Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, Maryland 20903

VIII. Term, Termination, and Modification:

This agreement, when accepted by all participating parties, will have an effective period of performance from the date of the latest signature until December 31, 2014 and may be modified or terminated by mutual written consent by both parties or may be terminated by either party upon a thirty-day advance written notice to the other.

APPROVED AND ACCEPTED FOR NORTHEASTERN UNIVERSITY
By Deborah Grupp-Patrutz
Title Director
Research Admin & Finance
Date 11/19/09

APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION
By
Title Director, CDER
Date 12/4/09

NU PI acknowledgement of Terms and Conditions:
Barry L. Karger
Signature

[FR Doc. E9–31195 Filed 1–4–10; 8:45 am]
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