300-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. To date, BMS has never marketed SUSTIVA (efavirenz) 300-mg tablets. In previous instances (see, e.g., 67 FR 79640, December 30, 2002 (addressing a relisting request for Diazepam Autoinjector)), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The petitioner identified no data or other information suggesting that SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale as a result of safety or effectiveness concerns. FDA has reviewed its files for records concerning the withdrawal of SUSTIVA (efavirenz) 300-mg tablets. There is no indication that the decision not to market SUSTIVA (efavirenz) 300-mg tablets commercially is a function of safety or effectiveness concerns, and no information has been submitted to the docket concerning the reasons for which SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that SUSTIVA (efavirenz) 300-mg tablets were withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that SUSTIVA (efavirenz) 300-mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list SUSTIVA (efavirenz) 300-mg tablets in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety and effectiveness. ANDAs that refer to SUSTIVA (efavirenz) 300-mg tablets may be approved by the agency, as long as they meet all relevant legal and regulatory requirements for approval of ANDAs.

Dated: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1748 Filed 2–1–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA 225–05–6001

Memorandum of Understanding Between the Food and Drug Administration, Duke University and Duke University Health System, Inc.

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, Duke University (DU) and Duke University Health System, Inc. (DUHS). The purpose of the MOU is to establish the terms of collaboration between FDA, DU and DUHS to support shared interests and will begin with an initiative entitled: The FDA, DU and DUMC Elective Program.

DATES: The agreement became effective September 18, 2006.

FOR FURTHER INFORMATION CONTACT: Nancy L. Pluhowski, Center for Devices and Radiological Health (HFZ–1), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2890.

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: January 25, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

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MEMORANDUM OF UNDERSTANDING
between
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
Center for Devices and Radiological Health (CDRH)
and
DUKE UNIVERSITY (DU) AND
DUKE UNIVERSITY HEALTH SYSTEM, INC. (DUHS)
DURHAM, NC

The United States Food and Drug Administration (FDA) and Duke University (DU) and the Duke University Health System, Inc. (DUHS). FDA, DU and DUHS have a shared interest in scientific progress and advancing the frontiers of medicine. All of these organizations are actively engaged in the exchange of scientific information in diverse fields of science that affect human and animal health and medicine. Duke University's mission includes a commitment to help those who suffer, cure disease and promote health through sophisticated medical research and thoughtful patient care. This mission is consistent with a fundamental part of FDA's mission- to protect and promote the public health. Both FDA and DU institutions endorse scientific training for government employees, academicians and students to establish a strong foundation in interdisciplinary science and medicine.

This Memorandum of Understanding (MOU) establishes terms of collaboration between FDA and DU and DUHS to support these shared interests and will begin with an initiative entitled: The FDA DU and DUHS Elective Program . This initiative will add a unique aspect to the training being provided to the next generation of health care professionals. Through the guidelines stated in this MOU, participants will have the opportunity to enhance their educational experience by participating in a CDRH Medical Device Fellowship Program (MDFP) rotation that will focus on medical device regulation and approval. Other opportunities such as sabbaticals, pre-doctoral and post-doctoral fellowships and student internships will be explored as this partnership develops.

Each party agrees to protect non-public Proprietary/Confidential Information. Proprietary/Confidential Information shall not be disclosed, copied, reproduced or otherwise made available to any person or entity without the consent of the owning Party except as required under court order or the Freedom of Information Act (5 U.S.C. 552). Parties participating in this MOU will further declare that they will be disqualified from participating in any FDA decisions regarding approval of products that may result directly from activities conducted under this MOU.

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I. Food and Drug Administration

For this initiative, CDRH MDFP participants may include DU and DUHS students, residents, fellows and faculty or staff. FDA CDRH will provide DU and DUHS participants the following:

- Opportunities to participate in training courses and seminars at FDA or web-based training provided through FDA CDRH and the CDRH Staff College, as resources permit.
- Opportunities to explore collaborative research with FDA CDRH faculty, residents, and staff, laboratories or affiliated facilities.
- Frequent communication with CDRH faculty and staff via face-to-face meetings, conference calls or teleconferences.
- Welcome to faculty, staff, and residents wishing to visit FDA.
- Communication of this collaborative effort through web pages, press releases, teleconferences, informal conversations with colleagues, faculty and students, joint conferences and symposia.
- Office space and/or laboratory facilities, as needed for research and review activities.
- Opportunities for candidates to serve as a CDRH Medical Device Fellows or Visiting Scholars.
- Opportunities for faculty to spend a sabbatical with the agency with terms of the sabbatical to be negotiated between the individual and the agency.
- Opportunity to obtain in-depth training in device review practices and policy via a 6 month residential training session.
- Opportunity to participate in reviews of medical devices and provide consultations, as appropriate, in their area of expertise from their home office after the 6 month residential training session.

Participants in this program will not be permitted to serve on device advisory panels reviewing a product for which they provided consultative or review services. Participants agree that they will be disqualified from any FDA decisions regarding approval of products that result directly from activities conducted under this MOU. The statutory provisions about former and post federal employment restrictions will apply to the participants in this program.

II. DU and DUHS; Durham, NC

DU and DUHS will provide FDA CDRH personnel the following:

- Laboratory and/or office space as needed.
- Proactive efforts in establishing collaborative research efforts.
- Continuing and frequent communication with DU and DUHS faculty and staff, to include face-to-face communication and teleconferences.

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- Welcome to FDA staff wishing to visit relevant DU and DUHS programs and laboratories.
- Communication of this collaborative effort through web pages, press releases, informal conversations with colleagues, faculty and students, joint conferences and symposia.
- Adjunct faculty appointments in relevant DU and DUHS programs or departments for those FDA staff members working with DU and DUHS students or residents and/or assisting in teaching at DU and DUHS.
- Encouragement of graduate students/residents to elect short-term opportunities in FDA review divisions and laboratories.
- Opportunity to attend graduate courses.
- Opportunity to visit and receive short term training at the DU and DUHS consistent with standard DU and DUHS policies, resources permitting.

In addition to the above, FDA CDRH via the MDFP will provide DU and DUHS candidates the following, as part of the Fellowship Program:

- DU and DUHS will pre-select the candidates that will be permitted to apply.
- FDA will select the participants, using mutually agreed upon criteria.
- Both parties will agree on a training/regulatory work plan of at least six (6) months in length.
- Consistent with DU and DUHS and FDA rules and regulations, and negotiated on a case-by-case basis, FDA mentors can, where appropriate, participate in other aspects of the candidate's educational program..
- As appropriate, openness and welcome to candidates interested in an opportunity to rotate through FDA centers, to obtain short-term training and hands-on experience.

Participants in this program will not be permitted to serve on device advisory panels reviewing a product for which they provided consultative or review services. Participants will agree that they will be disqualified from any FDA decisions regarding approval of products that result directly from activities conducted under this MOU. The statutory provisions about former and post federal employment restrictions will apply to the participants in this program.

III. Purpose

In the FDA DU and DUHS Elective Program , FDA and the three organizations will work cooperatively to give participants a better understanding of the medical product approval process, relevant FDA regulations and legislation, and the types of applications submitted for review.

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IV. Coverances

Patent, license, and other legal instruments will be prepared in accordance with federal law and DU and DUHS policy, and written notice referencing the policies will be provided to the individual prior to entering duty with FDA. DU and DUHS and FDA may decide to enter into a Cooperative Research and Development Agreement (CRADA) at a future time to conduct collaborative research and projects of mutual interest. The terms of such a CRADA will address Intellectual Property rights.

This MOU forms the basis for the initial relations between FDA and DU and DUHS for fellowship opportunities, sabbaticals, research, and scientific education. However, as this collaborative effort progresses, it is anticipated that new areas of mutual interest may be included in expansions of this document.

V. Finances and Resources

DU and DUHS and FDA agree that this MOU does not commit either party to make specific levels of financial or personnel support or to provide specific office or laboratory space for the programs and that the provision of such support will be based on available resources and provided in accordance with the rules, regulations and laws under which FDA operates and the policies of DU and DUHS.

VI. Citizenship and Security Clearance

DU and DUHS individuals participating in the MOU will be United States citizens or permanent residents. Regarding the latter, all federal restrictions will be adhered to. Information may be obtained from participants by the agency for security clearance or access to FDA facilities and offices. The information obtained may be re-disclosed to other Federal agencies for the above purposes and in fulfillment of official responsibilities to the extent that such disclosure is permitted by law.

VI. Protection of Non-Public Information

Residents, fellows, faculty and students appointed to a position at FDA will be required to sign a Commitment to Protect Non-public Information agreement. Whereas access to privileged information in the files of the Food and Drug Administration is required in the performance of official duties, the party 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 privileged information.

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VII. Conflict of Interest

Individuals must be free of conflict prior to performing his or her duties. Residents, fellows, faculty and students selected as a fellow or visiting scholar with FDA will be required to sign a Conflict of Interest Clearance agreement. Pursuant to the Ethics in Government Act of 1978, the parties may also be asked to file a financial disclosure report. The person responsible for the participants' assignments will be advised of any potential conflict so that conflicting assignments can be avoided, consistent with the agency's needs. If at any time prior to or during the performance of the assigned duties, the program participant believes that a potential or actual conflict exists, the individual must notify his or her supervisor and the FDA contact person indicated below on this agreement. A determination will be made by FDA/CDRH as to whether a conflict of interest exists and if real, how to resolve or mitigate it. Participants in the program will avoid activities or relationships that would cause a reasonable person to question the impartiality of his or her actions.

VIII. Contacts

The individual to whom all inquiries to FDA should be addressed is:

Nancy J. Pluhowski
Director, Medical Device Fellowship Program
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
9200 Corporate Blvd (HFZ-1)
Rockville, MD 20850
Phone: (301)827-2890
FAX: (301)443-1353
Email: nancy.pluhowski@.fda.hhs.gov

The individual to whom all inquiries regarding the FDA Duke University Elective Residency Program:

Diana B. McNeill, MD
Director, Residency Training Program
Duke University Medical Center
Box 3158
Durham, NC 27710
Phone: (919)684-3841
FAX: (919)668-1559
Email: mcnei006@mc.duke.edu

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The individual to whom all inquires regarding the Duke University Health System:

Malcolm Isley
Associate Vice President, Network Services
Duke University Health System
3100 Tower Blvd., Suite 600
Box 80
Durham, NC 27707
Phone: (919) 419-5033
FAX: (919) 493-9159
Email: malcolm.isley@duke.edu

AGREED TO:

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 9/18/06
Signature of authorized representative Date

Daniel G. Schultz, M.D.
Director, Center for Devices
Radiological Health (CDRH)

DUKE UNIVERSITY

BY: _____ 9-11-06
Signature of authorized representative Date

Gordon Williams
Vice Chancellor for Operations - DUMC

DUKE UNIVERSITY HEALTH SYSTEM, INC.

BY: _____ 9/4/06
Signature of authorized representative Date

Malcolm Isley
Associate Vice President, Network Services

BY: _____ 9/7/06
Signature of authorized representative Date

William J. Fulkerson, MD
Vice President, Acute Care Division

[FR Doc. 07–454 Filed 2–1–07; 8:45 am]
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