Corrections

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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4004]

Memorandum of Understanding Between the Food and Drug Administration and the Harvard–Massachusetts Institute of Technology Division of Health Sciences and Technology

Correction

In notice document 04–17513 appearing on page 46157 in the issue of Monday, August 2, 2004, make the following correction:

In the third column, after the file line, insert the following pages:

FINAL – 3/16/04

225-04-4004

Control No. _____

MEMORANDUM OF UNDERSTANDING
Between the

UNITED STATES FOOD AND DRUG ADMINISTRATION
And
HARVARD – MASSACHUSETTS INSTITUTE OF TECHNOLOGY
DIVISION OF HEALTH SCIENCES AND TECHNOLOGY (HST)

This Memorandum of Understanding between the U.S. Food and Drug Administration and HST is established to formalize an agreement to develop collaborative activities between the two parties in the areas of research, education, and outreach.

I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to establish the framework for a collaborative partnership on mutually agreed activities in the areas of scientific research and education. The United States Food and Drug Administration (FDA) and the Harvard-MIT Division of Health Sciences and Technology (HST) have a shared interest in advancing science in the pharmaceutical development and regulatory approval process through an exchange of scientific capital in the diverse fields of medical and biological sciences and engineering that directly and indirectly affect human health and medicine. Both institutions also endorse continued scientific training for regulatory scientists, academicians, and students to foster the well-grounded foundations in interdisciplinary science from which scientific learning will grow.

This MOU establishes terms of collaboration between FDA and HST to support these shared interests that can proceed through a variety of programs and subsequently executed agreements such as co-sponsorship of symposia and workshops, sabbaticals, postdoctoral fellowships, and student internships, and cooperative research and development agreements.

The intent of the collaborative partnership resulting from this MOU include: (1) development of a sound working relationship between U.S. Food and Drug Administration and HST, (2) provision of exchange of graduate and undergraduate students, faculty, and personnel, for the purposes of advanced training and outreach, and (3) stimulation of cooperative activities, research, and information exchange in areas such as bioimaging, combination tissue-engineered technologies, and clinical trial designs.

II. Background

The U.S. Food and Drug Adminstration has a primary role in advancing the translational /applied science that is needed to move promising new biomedical technologies into actual manufactured products in the most efficient manner possible while assuring the clinical safety and effectiveness of such products for patient care. The Harvard-MIT Division of Health Sciences and Technology (HST) is a research and education organization that combines faculty from MIT, Harvard University, Harvard-affiliated teaching hospitals and local pharmaceutical industries to provide a multidisciplinary/multiprofessional education and research experience that is equally divided among engineeering and physical sciences, biological sciences, and

FINAL – 3/16/04

clinical medicine. HST's research focuses on 1) structural and functional biomedical imaging, 2) functional and regenerative biomedical technologies, and 3) biomedical informatics and systems biology. These three areas are all of crucial importance to FDA to keep pace with cutting edge technologies requiring FDA review and approval.

III. Substance of Agreement

This Memorandum of Understanding is intended as a broad vehicle to promote programmatic interaction in the form of joint collaboration between FDA and HST researchers, students, and personnel as well as joint development of relevant projects.

The areas of collaboration will include but not be limited to the following:

Clinical trial designs. 1) A workshop and or conference focused on improving clinical trial designs in order to facilitate a more stream-lined process for evaluating healthcare products and services will be held that brings together FDA personnel, university and industry scientists, statisticians and bioethicists under a co-sponsorship agreement with HST to be executed subsequent to this MOU.
2) Joint research on the more theoritical statistical questions in this area.

Combination tissue-engineered products. Activities in this area will be based on mutually agreed upon collaborations centered around joint training activities. Training activities such as seminars, workshops or short courses arising from complementary interests may be developed jointly by HST and FDA and offered to FDA scientists and reviewers, HST scientists, industry, and others as identified needs arise. These exchanges could also include internships, research opportunities, and shadowing opportunities for HST post-baccalaureate and graduate students at the FDA. Faculty and senior staff from FDA, HST, and other partners will be encouraged to participate in this effort for mutual research and training interactions to possibly include short or long-term exchanges of staff (e.g. sabbaticals).

Imaging biomarkers. There are several areas of collaboration between FDA and HST relative to imaging biomarkers that have been identified as being mutually beneficial, including but not limited to:

1) Joint research programs. Joint research programs may be formed by scientists from the respective institutions with mutual complementary interests in certain areas such as validation or development of imaging biomarkers. This research may be based on collaborative analysis of data from FDA files and the literature, or experimental work. 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 and journal publications.

2) Joint participation and or sponsorship of conferences on issues related to imaging biomarkers, such as the definition of a valid imaging biomarker.

As specific topics for joint research are identified under this MOU they will be conducted under the appropriate formal agreements as required by law.

FINAL – 3/16/04

IV. Participants

A wide range of faculty and graduate students from programs including, but not limited to Biomedical Enterprises, Medical Sciences, Medical Engineering and Physics, Radiological Sciences, Clinical Investigator Training and Biomedical Engineering would be potential participants from HST. Senior scientists and policy officials from the Commissioners Office, and scientists and reviewers from the Product Centers and Offices of FDA would be participants from the FDA. Other participants could include scientists from industry, field laboratories and others identified for joint training and outreach activities.

V. Resource Obligations

This MOU describes in general terms the basis upon which the Parties intend to cooperate in these activities. 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 appropriated 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.

VI. Sharing of Information

Unless the law requires or permits such sharing, the parties will share only information that is not prohibited from disclosure to the public by law, e.g. the Freedom of Information Act.

VII. Name and Address of Participating Parties

A. Harvard–MIT Division of Health Sciences and Technology
Building E25-519
77 Massachusetts Avenue
Cambridge, MA 02139-4307

B. U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

VII. Liason Officers

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FINAL – 3/16/04

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VIII. Period of Agreement

This MOU shall become effective upon the signature of all the Parties and will continue in effect for five (5) years. It may be extended by mutual written agreement of the Parties in writing. It may be modified by mutual consent or terminated by either Party upon a 30-day advance notice to the other Party.

XI. Regulations

This MOU and all associated agreements will be subject to the applicable federal and state laws and regulations.

APPROVED AND ACCEPTED FOR THE HARVARD-MIT DIVISION OF HEALTH SCIENCES AND TECHNOLOGY

By _____

Title Director

HST

Date 3/29/04

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By _____

Title Commissioner,

FDA

Date 3/18/04

[FR Doc. C4–17513 Filed 8–20–04; 8:45 am]
BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–171386–03]

RIN 1545–BD16

Time and Manner of Making Section 163(d)(4)(B) Election To Treat Qualified Dividend Income as Investment Income

Correction

In proposed rule document 04–17797 beginning on page 47395 in the issue of Thursday, August 5, 2004 make the following correction:

On page 47395, in the third column, the subject heading is corrected to read as set forth above.

[FR Doc. C4–17797 Filed 8–20–04; 8:45 am]
BILLING CODE 1505–01–D