topics will be discussed: (1) The definition of quality, (2) mechanisms for implementing quality in clinical investigations, and (3) methods to improve the accuracy and reliability of collected data. As part of the Human Subject Protection/Bioresearch Monitoring Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*), this public workshop will help improve the safe conduct of clinical investigations and maximize efficiency in clinical investigations without compromising quality.

Dated: April 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8137 Filed 4–27–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–8001]

Memorandum of Understanding Between the National Cancer Institute and the Food and Drug Administration

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 the National Cancer Institute (NCI), part of the National Institutes of Health of the Department of Health and Human Services. The purpose of this MOU is to establish a formal collaboration between FDA and NCI regarding proteomics science and technology to accelerate proteomics technology development and application in clinical settings. FDA and NCI intend to collaborate in areas involving proteomics such as: Sample collection, preparation, storage and processing; bioinformatics and data analysis; discovery and validation of biomarkers; and surrogate biomarkers of cancer development and drug response, including standardization among technology platforms and assay standards development.

DATES: The agreement became effective April 5, 2007.

FOR FURTHER INFORMATION CONTACT: Francis Kalush, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0996, e-mail: *francis.kalush@fda.hhs.gov*.

or Henry Rodriguez, Office of the Director, (MSC–2580), National Cancer Institute, 31 Center Dr., rm. 10A52, Bethesda, MD 20892, 301–496–1550.

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: April 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

NATIONAL CANCER INSTITUTE

AND THE

U.S. FOOD AND DRUG ADMINISTRATION

National Cancer Institute – Food and Drug Administration

Memorandum of Understanding for Proteomics

The National Cancer Institute (NCI) and the Food and Drug Administration (FDA), within the United States Department of Health and Human Services agree that it is in the interests of both agencies to develop a partnership that leverages each agency's core expertise and resources. This partnership is intended to facilitate new science and technology initiatives to advance domestic and international public health through the development of targeted therapies based on patient proteomic profiles, ultimately decreasing death and suffering due to cancer and improving public health. Proteomics involves the study of proteins and their functions, and proteomics can be instrumental in discovery of biomarkers, including cancer markers. Although each agency has a unique mission, the NCI and FDA have mutual interests in understanding the molecular biology of cancer—NCI as the U.S. government's principal agency for cancer research and training, and FDA in promoting the public health by efficiently reviewing clinical research and product submissions. It is within the scope of these interests, as they pertain to proteomics technologies and proteomics applications in clinical cancer diagnostics and cancer therapeutics development, that this memorandum of understanding (MOU) is developed.

1. PURPOSE, BACKGROUND, AND SCOPE

The purpose of this MOU is to create a framework to foster scientific and programmatic collaborations. The collaborations envisioned by this MOU involve proteomics science and technology applications such as instrument/technology validation, informatics, biological sample preparation, diagnostics, and discovery and validation of biomarkers for cancer development, therapeutics, and response. This MOU sets forth the basic principles under which the agencies intend to work together to foster partnership in: research and education; the exchange of ideas, information, and data; the development and use of proteomics technologies that may be used by the NCI and other sponsors in clinical applications..

Achievements in science and technology now require a higher level of integration, particularly in the development of interdisciplinary research teams. As outlined next, the programmatic strengths and interests of the NCI and FDA in the areas of molecular biology, technology development, protein chemistry, analytical validation and clinical trials designs offer the opportunity for synergy that will accelerate proteomics technology development and application in clinical settings.

NCI Programs:

The NCI has recently launched the Clinical Proteomics Technology Initiative for Cancer (CPTI) to specifically address limitations and challenges in applying clinical proteomics to alleviate the cancer burden. The CPTI supports research, training, data collections and analysis, technology assessment, and other programs with respect to understanding and

analyzing the field of proteomics in order to improve technological capabilities in early detection, diagnostics, prevention, therapeutic monitoring, and treatment of cancer. The NCI has identified the development of high impact technologies to support cancer research as a priority area. The CPTI program will advance the field of proteomics to allow data and results to be compared and compiled to better understand changes in the proteome as they are reflected in cancer.

FDA Programs:

The FDA has launched the Critical Path Research Initiative to identify, develop, and apply state-of-the-art genomics and proteomics technologies to product characterization and clinical analytical design for faster, more predictable development and regulatory approval of safe and effective innovative medical products for cancer to enhance public health.

The FDA's Office for In Vitro Diagnostic Devices Evaluation and Safety (OIVD) in the Center for Devices and Radiological Health (CDRH) reviews premarket submissions for in vitro diagnostics, monitors their postmarket performance, and takes compliance actions when necessary. The development of appropriate measurement methods, standard protocols, and analysis platforms is essential for the integration into clinical settings of new technologies and molecular-based diagnostics.

The FDA's Center for Biological Evaluation and Research (CBER) ensures the safety, purity, potency, and effectiveness of biological products, including vaccines, blood and blood products, and cells, tissues, and gene therapies applicable to the prevention, diagnosis, and treatment of human diseases or conditions. Proteomics technologies are intrinsically related to the development and monitoring of therapies for safety, potency and efficacy, and will facilitate the availability of critical medical therapies to save lives and improve human health. CBER monitors numerous attributes of a product from development to postmarketing, and regulatory scientists at CBER are engaged in the Critical Path research and regulatory applications of proteomics technologies.

The FDA's Center for Proteomics and Center for Toxicoinformatics within the National Center for Toxicological Research (NCTR) conduct research in support of the FDA's current and future regulatory needs. The Center for Proteomics currently has a research emphasis in the development of mass spectrometry-based proteomic methods as well as in the development of proteomic informatics tools to aid in data analysis (in collaboration with the Center for Toxicoinformatics). The Center for Toxicoinformatics continues development of technologies to incorporate, manage, and analyze data from proteomic experiments to improve sponsor data submission channels.

This MOU is intended to enable and encourage the sharing of knowledge between FDA and NCI programs to solve complex problems in the area of each agency's mission. The parties agree to collaborate to develop strategic plans, set priorities, and leverage expertise, as appropriate, from multiple sources, including the private sector.

Projects undertaken pursuant to this MOU are intended to facilitate the transfer of science, technology, and engineering discoveries developed through the CPTI to clinical settings by working with the expertise of the FDA in product characterization, and analytical and clinical validation. Important areas of mutual interest include the application of proteomics technologies to disease diagnostics, product characterization, safety assessment, and therapeutic monitoring. Both agencies depend on the reproducibility of results to ensure accurate clinical applications. In order for the field of proteomics to advance and move into clinical settings, both agencies would benefit from exchanges of information on analytical and clinical validation of proteomic technologies, proteomic data submission requirements, and the subsequent results and interpretations of such data.

2. AUTHORITY

This MOU is authorized under Section 301 of the Public Health Service Act which authorizes NIH to cooperate with public authorities and scientific institutions and Section 903 of the Federal Food, Drug, and Cosmetic Act. This MOU is also consistent with FDA's statutory charge to foster collaboration with other science-based agencies to enhance the scientific and technical expertise available to the FDA in the conduct of its duties with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies.

3. COLLABORATION

The parties intend to collaborate in areas involving proteomics, including: sample collection, preparation, storage, and processing, bioinformatics and data analysis, diagnostic assay development, and discovery and validation of biomarkers and surrogate biomarkers of cancer development and drug response, including standardization among technology platforms and assay standards development.

a. Coordination and cooperation may include but is not limited to the specific areas identified below:
    i. Development of best practices for data submission and analysis parameters for use by proteomics data repositories
    ii. Development of joint educational material and programs in which NCI and FDA detail the current best practices for proteomics technologies and applications
    iii. Formation of NCI, FDA, academic, industry and other government agency partnerships to improve proteomics standard operating procedures
    iv. Use of facilities, software, algorithms, and data repositories
    v. Cooperation to facilitate and enhance extramural research and development activities by either agency
    vi. Cooperation through the exchange of agency expertise, scientific and technical information, data, and publications

vii. Joint publicity of mutually reinforcing activities, publications, and research results, including hyperlinks to each others' programs on their websites
viii. Mutual assistance in program planning, and in the review of research development projects and proposals
ix. Inclusion of representatives from each agency in workshops, working groups, seminars, and other related activities.
x. Joint educational seminars and workshops to make the scientific community aware of the research in applied and clinical proteomics, reduce redundant studies, and improve the efficiency of technology validation
xi. Educational seminars by FDA for NCI , its funded institutions, and other stakeholders on the current requirements, parameters, and concerns in regulatory data submissions for products based on proteomics data.

b. To pursue the collaboration described above, the parties agree to use the following framework for implementing collaborations:
   i. Both the NCI and FDA will identify coordinators to implement and manage this MOU. The Director of the NCI's Clinical Proteomic Technologies Initiative for Cancer and the Director of the FDA's Office for In Vitro Diagnostic Devices Evaluation and Safety in the Center for Devices and Radiological Health, or their designees, will be the primary representatives to coordinate the activities from their respective agencies for the purposes of this MOU. The coordinators shall meet on a regular basis to discuss activities conducted under the MOU, review all aspects of implementation, and plan future directions of programmatic interaction and cooperation, and report to signatories annually.
   ii. Concepts or ideas for developing collaborations or activities involving joint projects or integrated approaches to conducting science or technology development will be presented by submission of concepts to the coordinators of the MOU.
   iii. Representatives from each agency will meet quarterly to review progress and address new opportunities for collaboration. Technical and programmatic working groups made up of NCI and FDA employees may be assembled to make formal recommendations for collaboration.
   iv. Industry and scientific organizations' representatives for relevant proteomic technologies may interact with each agency in accord with regulations and guidance issued by each agency.

c. Cost and funding
   i. None of the activities outlined above involves the exchange of funds between NCI and FDA.
   ii. The NCI and FDA agree that this MOU does not commit either agency to make specific levels of financial or personnel support or to provide specific laboratory or office space for programs relevant to this MOU. The provision of such support will be based upon available resources and provided in accordance with the law.

4. INFORMATION-SHARING, TECHNOLOGY TRANSFER AND INTELLECTUAL PROPERTY

The parties shall share and disclose information in compliance with applicable laws and regulations. Implementing agreements may address particular information exchange or disclosure issues more specifically

5. CONTACTS

Notices or formal communications pursuant to this MOU should be sent to:

For FDA: Francis Kalush, Ph.D
OIVD, CDRH
2098 Gaither Rd
HFZ-440
Rockville, MD. 20850
Telephone: (240) 276-0996

For NCI: Henry Rodriguez., Ph.D., M.B.A.
Office of the Director, NCI
31 Center Drive
MSC 2580 - Room 10A52
Bethesda, MD 20892
Telephone: (301) 496-1550

6. DURATION OF MOU, MODIFICATIONS, AND TERMINATION

This MOU, when agreed to by the Parties, will have an effective date from the date of the last to sign and will remain in effect for five (5) calendar years from the effective date, unless modified by the mutual agreement of the parties upon sixty days notice in writing. Either party may terminate this MOU at any time provided a 90-day advance written notice is provided to the other agency and appropriate steps are taken to ensure an orderly termination of joint activities.

AGREED TO:

UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 4/6/07
Signature of authorized representative Date

Janet Woodcock, M.D.
Deputy Commissioner and Chief Medical Officer,
U.S. Food and Drug Administration (FDA)

NATIONAL CANCER INSTITUTE

BY: _____ 04/04/07
Signature of authorized representative Date

Anna Barker, Ph.D.
Deputy Director for Strategic Scientific Initiatives and Partnerships
National Cancer Institute

BY: _____ 04-05-07
Signature of authorized representative Date

John E. Niederhuber, M.D
Director, National Cancer Institute
National Institutes of Health

EFFECTIVE DATE

This MOU is effective on the date of the last to sign.

[FR Doc. 07–2106 Filed 4–27–07; 8:45 am]
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