either be issued on a Notice of Grant Award (PHS 5152) signed by the FDA Chief Grants Management Officer and be sent to the applicant by mail or transmitted electronically.

2. Administrative and National Policy Requirements

These agreements will be subject to all policies and requirements that govern the research grant programs of PHS, including provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and the PHS Grants Policy Statement.

Applicants must adhere to the requirements of this notice. Special terms and conditions regarding FDA regulatory requirements and adequate progress of the study may be part of the awards notice.

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at *http://www.healthypeople.gov/* under ''Publications.'' (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

3. Reporting

A. Reporting Requirements

The original and two copies of an annual Financial Status Report (FSR) (SF–269) must be sent to FDA's grants management officer within 90 days of the budget period end date of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant. A final FSR will be due 90 days after the expiration of the project period as noted on the Notice of Grant Award.

For continuing cooperative agreements, quarterly reports and an annual program progress report are also required. For such cooperative agreements, the noncompeting continuation application (SF 424/PHS 5161–1) will be considered the program progress report for the fourth quarter of the budget period.

Quarterly progress reports must contain, but are not limited to the following:

1. A status report on the installation, training, and operational readiness of any equipment that is provided;

2. A summary report on any proficiency testing performed;

3. A summary status of samples analyzed and time to complete individual sample testing; and

4. A summary description of any other testing performed on the equipment.

A final program progress report, FSR, and invention statement must be submitted within 90 days after the expiration of the project period as noted on the Notice of Grant Award.

The final program progress report must provide full written documentation of the project, and summaries of laboratory operations, as described in the grant application. The documentation must be in a form and contain sufficient detail such that other State, local, and tribal government FERN laboratories could reproduce the final project.

B. Monitoring Activities

The program project officer will monitor grantees periodically. The monitoring may be in the form of telephone conversations, e-mails, or written correspondence between the project office/grants management office and the principal investigator. Periodic site visits with officials of the grantee organization may also occur. The results of these monitoring activities will be recorded in the official grant file and will be available to the grantee upon request consistent with applicable disclosure statutes and with FDA disclosure regulations. Also, the grantee organization must comply with all special terms and conditions of the cooperative agreement, including those which state that future funding of the study will depend on recommendations from the project officer. The scope of the recommendation will confirm that: (1) There has been acceptable progress on the project; (2) there is continued compliance with all FDA regulatory requirements; (3) if necessary, there is an indication that corrective action has taken place; and (4) assurance that any replacement of personnel will meet the testing requirements.

VII. Agency Contacts

Regarding the administrative and financial management aspects of this notice: Michelle Caraffa (see *Addresses to Request Application* in section IV of this document).

Regarding the programmatic or technical aspects of this notice: Alexandra Cossi, Division of Federal State Relations, Office of Regulatory Affairs, Food and Drug Administration (HFC–140), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–2899, e-mail: *alexandra.cossi@fda.hhs.gov*.

VIII. Other Information

Data included in the application, if restricted with the legend specified in this section of the document, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act and FDA's implementing regulations (21 CFR 20.61).

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552), as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–7124 Filed 8–21–06; 12:49 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8403]

Memorandum of Understanding Between the U.S. Food and Drug Administration, the National Cancer Institute, and the National Institute of Standards and Technology

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Memorandum of Understanding (MOU) is to set forth an agreement between the National Cancer Institute (NCI), the National Institute of Standards and Technology (NIST), and the Food and

Drug Administration (FDA) (collectively ''the Parties'', or individually as a ''Party'') regarding the roles, responsibilities, and financial commitments of each Party relating to the collaboration through working groups and steering committees to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goal of facilitating the development of nanotechnologies that constitute novel research tools and safer, more effective cancer therapies by establishing a framework for effective risk identification, assessment and evaluation of emerging products based on nanotechnology. This collaboration among the Parties will be focused primarily on the Nanotechnology Characterization Laboratory and directly related activities.

DATES: The agreement became effective June 22, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Senior Scientific Advisor, Office of the Commissioner (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7867, FAX: 301–443–9718.

For NCI: Gregory J. Downing, Director, Office of Technology and Industrial Relations, Office of the Director, National Cancer Institute, 31 Center Dr., rm. 10A52, Bethesda, MD 20892, 301–496–1550, FAX: 301–496–7807.

For NIST: Debra Kaiser, Chief, Ceramics Division, Materials Science and Engineering Laboratory, National Institute of Standards and Technology, 100 Bureau Dr., Stop 8522, Gaithersburg, MD 20899, 301–975–6119, FAX: 301–975–5334.

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: August 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

FDA No. 225-06-8403

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION (FDA)

THE

THE NATIONAL CANCER INSTITUTE (NCI)

AND THE

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)

FOR THE

NANOTECHNOLOGY CHARACTERIZATION LABORATORY (NCL)

AND

RELATED NANOTECHNOLOGY ACTIVITIES

Whereas extensive cross-sector and multi-disciplinary efforts are needed to understand and develop nanotechnology-based platforms and tools for cancer research as well as diagnostic and therapeutic applications;

Whereas the FDA, NCI, and NIST, hereafter referred to as the Parties, find that it is in the best interests of the three Parties (NCI is an institute within an agency, NIH) to develop a partnership that leverages each Party's core expertise and resources to facilitate nanotechnology development that will lead to new clinical products;

Whereas FDA, with its unique perspective on research and development activities and in-depth understanding of clinical trial design, regulatory policy, and scientific know-how in reviewing medical products, is interested in anticipating the impact of nanotechnology development and facilitating regulatory review and evaluation of new medical products that incorporate nanotechnology by working to clearly establish the critical path for such impending applications;

Whereas NCI, with its significant cancer research infrastructure and advanced technology programmatic investments, is interested in eliminating suffering and death due to cancer and seeks to develop technologies to improve the detection, diagnosis, treatment, and prevention of cancer;

Whereas NIST, with it world-class metrology facilities and standardization capabilities and expertise, is interested in improving translational research, commercialization, and national economy overall;

Whereas the private sector has expressed interest in further scientific exploration and nanotechnology development for novel diagnostic and therapeutic application;

Whereas FDA and NCI formed an Interagency Oncology Task Force (IOTF) in 2003 whose nanotechnology subcommittee, with a mission to foster greater understanding of the biomedical applications of nanotechnology, directly supports this Memorandum of Understanding (MOU) to support collaborations on oncology-related issues in nanotechnology development for clinical benefit, and standardization of approaches for evaluating nanotechnology devices and materials for cancer diagnosis and treatment;

Now, therefore, the Parties agree to collaborate through working groups and steering committees to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goal of facilitating the development of nanotechnologies that constitute novel research tools and safer, more effective cancer therapies by establishing a framework for effective risk identification, assessment, and evaluation of emerging products based on nanotechnology. This MOU sets forth the framework for collaboration among the Parties and for pursuing specific collaborative projects that may involve additional partners and will be implemented through separate agreements, as needed. This collaboration among the Parties will be focused primarily on the Nanotechnology Characterization Laboratory (NCL) and directly related activities. The Parties anticipate that concepts developed and activities undertaken under the auspices of this MOU may lead to partnerships that will be implemented through separate agreements.

The Parties agree as follows:

RESPONSIBILITIES OF THE PARTIES

In order to pursue the goals described above, the Parties agree to work through the process described below.

1. The Parties will collaborate on nanotechnology characterization and related development activities, primarily in the context of the NCI's NCL. Through this collaboration, the Parties intend to share best practices and know-how with each other, and will provide access to data regarding the assessment tools for use in FDA's regulatory evaluation and guidance development to facilitate cancer drug development. The close collaboration among the Parties, including sharing of data, characterization approaches, and best practices, is expected to a) support understanding and resolution of potential implications of nanotechnology-based products for clinical application; b) facilitate the development of measurement methods and standard protocols appropriate to innovative and disruptive technologies; and c) facilitate transfer of cancer science and engineering discovery and development through commercialization, with the measurement science and standards programs and regulatory science and evaluation policy development.

2. Within the framework of this MOU, related collaborations and separate agreements may be developed as appropriate, and may include, but may not be limited to the following areas and activities, as time and staff resources permit:

   i. Development and refinement of the preclinical and early clinical pathway(s) for nanotechnology-based drugs and diagnostic devices to guide NCI-supported technology development leading to medical products;
   ii. Development and validation of standards, risk/benefit analyses and other evaluative tools to identify risks and assess safety and efficacy in newly emerging nanotechnology-based products;
   iii. Development of publicly available master files containing data, e.g. protocols, assay cascades and other pre-competitive tools developed collaboratively by the Parties and that may guide further development of the field;
   iv. Development, validation and assessment of assays and other appropriate test methods, including close review and input from all Parties prior to standardization of those assays;
   v. Development of joint research programs that fund academic scientists or trainees identified under the joint IOTF training program to perform research at FDA and NIST in collaboration with FDA and NIST scientists, respectively, as well as potential research collaborations in the NCL by FDA and NIST scientists;
   vi. Representation for each agency on the Nanotechnology Characterization Laboratory Scientific Oversight Committee; and
   vii. Development of scientific collaborations to capitalize on opportunities generated by NCL activities.

3. Additional concepts or ideas for developing collaborations or activities involving joint projects or integrated approaches to conducting science or technology development specifically aimed at commercializing products will be formally presented by submission of concepts to the designated contact from each Party. These designated contacts will meet quarterly to review progress and address new opportunities for collaboration. When necessary, technical and programmatic advisory working groups made up of employees from the respective agencies may be assembled to make formal recommendations for collaboration. The designated contacts shall obtain appropriate agreement by each agency, in writing, on each significant activity to be undertaken pursuant to this MOU, including agreement on the scope of work; tasks, deliverables (if any) and delivery dates; anticipated products and outcomes; periods of performance; levels of funding and resources to be provided for each activity by the Parties; parameters of data sharing in compliance with all applicable statutory and regulatory requirements; and any other appropriate and necessary aspects of mutual activities. The designated contacts shall seek to resolve any dispute concerning the MOU through good-faith discussions.

4. To the extent that implementation of specific projects involves working with the non-federal government sector, the Parties will, consistent with all applicable statutory and regulatory requirements, facilitate dialogue with the appropriate potential collaborators or partners of interest, and commemorate agreements with non-federal entities in writing. Such interactions with the non-federal government sector may include a range of stakeholders, such as private non-profit organizations, industry, industry trade organizations, academic institutions, professional organizations, and patient advocacy groups.

5. In addition to nanotechnology characterization activities, the Parties will collectively develop and validate standards, nomenclature, assessment tools, and toxicology approaches to facilitate and accelerate the development of, and the evidence base for, new diagnostics and anticancer drugs within the applicable statutory and regulatory framework. The parties will also develop educational tools to make this information more widely available to patients, clinicians, and researchers.

GENERAL PROVISIONS

1. Proprietary and/or nonpublic information will not be disclosed under this MOU, unless such disclosure is governed by appropriate confidentiality disclosure agreements, or to the extent such disclosure is permitted by law.

2. It is understood that while the Parties have aligned interest, there may be opportunities for independent collaborations and activities outside the scope of this MOU, but which are under their respective public health missions. As such, the Parties may, as appropriate, enter into independent negotiations and agreements with prospective partners. All such agreements shall be in writing and in compliance with all applicable legal requirements.

3. A member of the NCL Scientific Oversight Committee shall recuse him/herself from any review of data if such a representative is involved in related activities or agreements with outside partners.

SIGNATURES OF RESPONSIBLE PARTIES

We, the undersigned, agree to abide by the terms and conditions of this MOU.

APPROVED AND ACCEPTED FOR THE FDA

Date 6/22/00

Janet Woodcock, M.D.
Deputy Commissioner for Operations
and Chief Operating Officer (COO)
U.S. Food and Drug Administration

APPROVED AND ACCEPTED FOR THE NCI

Date 06/15/06

Anna D. Barker, Ph.D.
Deputy Director
National Cancer Institute

APPROVED AND ACCEPTED FOR THE NIST

Date 6/19/06

William Jeffrey, Ph.D.
Director
National Institute of Standards and Technology

[FR Doc. 06–7127 Filed 8–23–06; 8:45 am]
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