approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: March 29, 1998. The applicant claims February 26, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: April 29, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for MYCAMINE (NDA 21–506) was initially submitted on April 29, 2002.

3. *The date the application was approved*: March 16, 2005. FDA has verified the applicant's claim that NDA 21–506 was approved on March 16, 2005.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,814 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination byMay 19, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 18, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions are to be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 13, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–3956 Filed 3–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8001]

Memorandum of Understanding Between the United States Food and Drug Administration, the National Cancer Institute, and the Centers for Medicare and Medicaid Services

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 Food and Drug Administration (FDA), the National Cancer Institute (NCI), and the Centers for Medicare and Medicaid Services (CMS) to develop strategic plans, set priorities, and leverage resources and expertise from multiple sources, including the private sector, toward the goal of improving the clinical utility of biomarker technologies as diagnostic and assessment tools that facilitate the development of safer and more effective cancer therapies. This collaboration among FDA, NCI, and CMS shall be known as the Oncology Biomarker Qualification Initiative.

DATES: The agreement became effective January 23, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane (HF–1), Rockville, MD 20857, 301–827–7861, FAX: 301–443–9718.

For NCI: Gregory J. Downing, Office of Technology and Industrial Relations, Office of the Director, National Cancer Institute, 31 Center Dr., MSC 2580—rm. 10A52, Bethesda, MD 20892, 301–496–1550, FAX: 301–496–7807.

For CMS: Peter Bach, Centers for Medicare and Medicaid Services, 20 Independence Ave., SW. (rm. 314G), Washington, DC 20201, 202–205–5610, FAX: 202–690–6262.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: March 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

FOOD AND DRUG ADMINISTRATION (FDA)

THE

THE NATIONAL CANCER INSTITUTE (NCI)

AND THE

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

FOR THE

FDA/NCI/CMS ONCOLOGY BIOMARKER QUALIFICATION INITIATIVE

Whereas extensive cross-sector and multi-disciplinary efforts are needed to understand and develop the clinical utility of a new generation of biomarker[1] technologies, which can be used for detection, diagnostic, and clinical assessment tools in cancer research;

Whereas such new biomarker technologies, if proven effective in assessing therapeutic response in clinical trials and thereby "qualified" have the potential to be adopted by the FDA as assessment tools for use in FDA guidance on cancer drug development;

Whereas CMS is interested in the development of evidence to inform reimbursement decisions making about existing or new treatment regimens;

Whereas the NCI 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 the private sector has expressed interest in further scientific exploration of biomarkers and associated technologies to enhance diagnostics and therapeutic development;

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 exploring biomarker technologies as assessment tools for use in FDA guidance to facilitate cancer drug development;

Whereas FDA and NCI formed an Interagency Oncology Task Force (IOTF) in 2003 that as a convening body serves as the source of the concept of this memorandum of understanding (MOU) to support collaborations on oncology-related issues including development and qualification of biomarkers and predictive tools (e.g., molecular assays and targeted therapies) for clinical benefit, and standardization of approaches for evaluating biomarkers and tools in diagnosing, staging, and assessing therapeutic response in cancer clinical trials;

Now, therefore, these three agencies 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 improving the clinical utility of biomarker technologies as diagnostic and assessment tools that facilitate the development of safer and more effective cancer therapies. This MOU sets forth the framework for collaboration among the three Parties and for pursuing specific collaborative projects that may involve additional Parties and will be implemented through separate agreements, as needed. This collaboration among FDA, NCI, and CMS shall be known as the Oncology Biomarker Qualification Initiative (OBQI). The Parties anticipate that ideas and concepts developed by the OBQI working groups and steering committees may lead to partnerships that will be implemented through separate agreements.

The Parties agree as follows:

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[1] Biological marker (biomarker) is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention. Clin Pharmacol Ther 2001;69:89-95.

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 form cross agency working groups to develop concepts for potential pursuit as a OBQI activity. These working groups shall be formed to consider approaches for the development and application of clinical assessment or biomarker technologies that enhance diagnostic or therapeutic strategies for various forms of cancer. Specific areas of scientific activities include the application of platform technologies for assessing genomic and proteomic alterations, multiplexed molecular assays, and advanced imaging modalities. Each working groups shall be responsible for developing and prioritizing concepts, preparing white papers on scientific rationale, evaluating availability technologies, addressing general concepts in experimental design, prepare protocols to evaluate biomarkers in clinical trials, and outlining approaches for assessing research progress. Moreover, the working group shall consider development of standards, nomenclature and tools to facilitate and accelerate the development of, and evidence base for, new diagnostics, assessment tools, and cancer therapeutics. As a result of this process the working groups will aim to increase the scientific knowledge base of specific biomarkers for various forms of cancer. The working groups will include representatives from each party and meet or conference monthly. The working group chairs will report to the OBQI chairs. A quarterly meeting will be held to discuss progress, develop consensus on working group activities, and foster communications and directions for facilitating the project(s).

2. Top priority projects that emerge from the working groups will be publicized as areas of interest of the OBQI with the intention of involving participation and input from private sector partners. Through this process, the government will seek to engage the private sector in the implementation of the research. Numerous implementation strategies are anticipated and available. These strategies may include the following: The federal government may perform certain research projects directly or through funding agreements. The private sector may perform projects directly or may fund the research through gifts to the government or through certain non-profit organizations, such as the Foundation for the National Institutes of Health. Consortiums of interested Parties may also be formed with different Parties responsible for different components of a project. To the extent that the federal government is involved in the implementation of projects, each agency is bound to act within its statutory authorities.[2]

3. To the extent that implementation of specific projects involves working with the non-federal sector, the Parties will, consistent with their legal authorities, facilitate dialogue with the appropriate potential collaborators or Parties of interest. Such interactions may include a range of stakeholders, such as private non-profit organizations, industry,

[2] To the extent that Federal employees are involved in the implementation of specific projects, federal employee participation will be governed by statutes, regulations and policies on interactions with outside organizations. Determinations of what is or is not permissible will be determined on a case by case basis.

industry trade organizations, academic institutions, professional organizations, and patient advocacy groups.

4. In addition to developing concepts for biomarker projects, the OBQI will develop standards, nomenclature and tools to facilitate and accelerate the development of, and the evidence base for, new diagnostics, assessment tools and anticancer drugs, and develop educational tools to make this information more widely available to patients, clinicians and researchers.

GENERAL PROVISIONS

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.

Any notice or other communication required or permitted under this MOU shall be in writing and will be deemed given as of the date it is received and accepted by the receiving party.

CONTACTS

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

For FDA: Wendy R. Sanhai, Ph.D.
Senior Scientific Advisor
Office of the Commissioner, FDA
5600 Fishers Lane HZ-1
Rockville, MD. 20857
Phone: (301) 827-7867, Fax (301) 443-9718

For NCI: Gregory J. Downing, D.O., Ph.D.
Director, Office of Technology and Industrial Relations
Office of the Director, NCI
31 Center Drive
MSC 2580 - Room 10A52
Bethesda, MD 20892
Telephone: (301) 496-1550, Fax: (301) 496-7807

For CMS: Peter Bach, M.D.
Policy Advisor, CMS
200 Independence Avenue, SW (Room 314G)
Washington, D.C., 20201
Telephone: (202) 205-5610, Fax: (202) 690-6262

TERM, TERMINATION AND MODIFICATIONS

1. This MOU constitutes the entire agreement among the Parties pertaining to the OBQI.

2. There are no representations, warranties, agreements or understandings, express or implied, written or oral between the Parties hereto relating to the subject matter of this MOU that are not fully expressed herein.
3. No supplements, amendments or modifications to this MOU shall be binding unless executed in writing, with thirty (30) days advance notice, and by mutual consent of the Parties; such modifications are to take the form of amendments.
4. This MOU, when accepted by the Parties, will have an effective date from date of the last to sign and will remain in effect for three (3) calendar years from the effective date unless modified or terminated.

Signatures begin on next page

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 1/24/06

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 01/20/06

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

APPROVED AND ACCEPTED FOR THE CMS

Barry M. Straube, M.D.

Date 01/23/2006

Barry Straube, M.D.
Acting Director, Office of Clinical Standards and Quality
The Centers for Medicare and Medicaid Services

[FR Doc. 06–2656 Filed 3–17–06; 8:45 am]
BILLING CODE 4160–01–C