

**ACTION:** Notice of extension of application deadline.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an extension for acceptance of applications to its continuous marketing applications (CMA) Pilot 2 program implemented under the guidance for industry entitled "Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." The extension applies only to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) review divisions that have not received acceptable applications for participation in the Pilot 2 program.

**DATES:** Submit written or electronic comments on agency guidances at any time. FDA will accept applications through December 31, 2004, for participation in the CMA Pilot 2 program per the restrictions described in the **SUMMARY** section of this document.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist either office in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:**

John Jenkins, Center for Drug Evaluation and Research (HFD-020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301-594-3937, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 6, 2003 (68 FR 57696), FDA announced the

availability of a guidance entitled "Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA." This guidance is one in a series of guidance documents that FDA agreed to draft and implement in conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA). The guidance discusses how the agency will implement a CMA Pilot 2 program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of development for certain Fast Track drug and biological products.

Under the CMA Pilot 2 program, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to be considered for participation in the CMA Pilot 2 program. The CMA Pilot 2 program is an exploratory program, and FDA will evaluate its impact on the investigational phase of drug development. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. The guidance provides information regarding the selection of applications for the CMA Pilot 2 program, the formation of agreements between FDA and applicants on the investigational new drug (IND) communication process, and other procedural aspects of the CMA Pilot 2 program.

Per section III.A.4 of the guidance, applicants were originally asked to apply for participation in the CMA Pilot 2 program from October 6, 2003, through December 8, 2003. For review divisions that had not received any acceptable CMA Pilot 2 program applications by December 8, 2003, applications were also accepted between February 9, 2004, and September 30, 2004. This notice further extends that deadline to December 31, 2004, to ensure inclusive and relevant results from the CMA Pilot 2 program. A description of the application submission process, evaluation criteria, and selection process is in the guidance. Applications will be accepted only in CDER and CBER divisions that have not previously selected a Pilot 2 application. Information regarding the CDER and CBER divisions that are available to select the CMA Pilot 2 program application can be found on FDA's Web site at <http://www.fda.gov/cder/pdufa/CMA.htm>. For each of these divisions, the first application received that adequately meets the evaluation

criteria will be accepted into the CMA Pilot 2 program and applicants will be informed within 6 weeks of application submission.

**II. Electronic Access**

Persons with access to the Internet can obtain the guidance at <http://www.fda.gov/cder/guidance/index.htm> or at <http://www.fda.gov/cber/guidelines.htm>.

Dated: November 15, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-25799 Filed 11-17-04; 1:52 pm]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004D-0460]

**Draft Guidance for Industry on Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers; Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of November 4, 2004. This document announced the availability of a draft guidance for industry entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers." The document was published with an incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:**

Joyce A. Strong, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 04-24675, appearing on page 64314 in the **Federal Register** of Thursday, November 4, 2004, the following correction is made:

1. On page 64314, in the second column, "Docket No. 2004N-0087" is corrected to read "Docket No. 2004D-0460".

Dated: November 12, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-25647 Filed 11-18-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Best Practices for the Licensing of Genomic Inventions

**AGENCY:** National Institutes of Health, Public Health Service, Health and Human Services (HHS).

**ACTION:** Notice of proposed best practices for the licensing of genomic inventions; request for comments.

**SUMMARY:** The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. PHS seeks to maximize the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. These best practices for the licensing of government-funded genomic inventions are recommendations to the intramural PHS technology transfer community as well as to PHS funding recipients.

**DATES:** Comments must be received no later than January 18, 2005.

**ADDRESSES:** Comments on the proposed best practices must be submitted to: Dr. Bonny Harbinger, Office of Technology Transfer, National Institutes of Health, 6011 Executive Blvd., Suite 325, Rockville, Maryland, 20852; telephone: (301) 594-7700; e-mail: [harbingb@mail.nih.gov](mailto:harbingb@mail.nih.gov).

#### SUPPLEMENTARY INFORMATION:

#### Best Practices for the Licensing of Genomic Inventions

##### Introduction

The Public Health Service's (PHS) primary mission is to acquire new knowledge through the conduct and support of biomedical research to improve the health of the American people. This mission is advanced by the intramural research efforts of government-owned and -operated laboratories and by the extramural research efforts funded through grants and contracts. PHS seeks to maximize the public benefit whenever PHS owned or funded technologies are transferred to the commercial sector. Motivated by this goal, we offer the following best practices for the licensing of government-funded genomic inventions.

Genomic inventions include a wide array of technologies and materials such as cDNAs; expressed sequence tags (ESTs); haplotypes; antisense molecules; small interfering RNAs (siRNAs); full-length genes and their expression products; as well as methods and instrumentation for the sequencing of genomes, quantification of nucleic acid molecules, detection of single nucleotide polymorphisms (SNPs), and genetic modifications. Much of the value associated with the commercial use of these technologies involves nucleic acid-based diagnostics, potential gene therapy applications, and the development of new DNA- and RNA-based therapeutics.

##### Background

Among the benefits derived from PHS-conducted and -supported biomedical research are effective and accessible new healthcare treatments and services. Practical realization of these benefits depends on the ability and willingness of private sector partners to develop and commercialize new technologies arising from PHS conducted and funded research. For potential preventive, diagnostic, and therapeutic products, the interest of the private sector in commercializing new technologies often depends on the existence of patent protection on the technology in the United States and foreign countries.

The Bayh-Dole Act of 1980 allows PHS grantees and contractors to seek patent protection on subject inventions made using Government funds and to license those inventions with the goal of promoting their utilization, commercialization, and public availability. Recipients of PHS grants and contracts have a role in implementing the requirements of the Bayh-Dole Act (<http://s-edison.info.nih.gov/iEdison/www.iedison.gov>). In 1986, Federal laboratories, including PHS research laboratories at the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC), were given a statutory mandate under the Federal Technology Transfer Act (Pub. L. 99-502) and Executive Order 12591 to ensure that new technologies developed in those laboratories were transferred to the private sector and commercialized.

PHS recognizes that patenting and licensing genomic inventions presents formidable challenges for academic and government technology transfer programs because of the complexities in bringing these technologies to the marketplace in a way that balances the

expansion of knowledge and direct public health benefit with the commercial needs of private interests.

The following represents best practices recommendations to the intramural PHS technology transfer community as well as to universities, hospitals and other non-profit PHS funding recipients. These recommendations are not intended to constitute additional regulations, guidelines or conditions of award for any contract or grant, although they are consistent with existing policies set out in Sharing Biomedical Research Resources ([http://ott.od.nih.gov/NewPages/RTguide\\_final.html](http://ott.od.nih.gov/NewPages/RTguide_final.html)) and Developing Sponsored Research Agreements (<http://ott.od.nih.gov/NewPages/text-com.htm>).

##### Patent Protection

Like other emerging technology areas, patents directed to genomic inventions tend to issue with claims that are broad in scope. Public health-oriented technology transfer must balance the rewards of broad intellectual property protection afforded to founders of enabling genomic inventions with the benefits of fostering opportunities for those striving to improve upon those innovations.

Therefore, in considering whether to seek patent protection on genomic inventions, institutional officials should consider whether significant further research and development by the private sector is required to bring the invention to practical and commercial application. Intellectual property protection should be sought when it is clear that private sector investment will be necessary to develop and make the invention widely available. By contrast, when significant further research and development investment is not required, such as with many research material and research tool technologies, best practices dictate that patent protection rarely should be sought.

##### Best Licensing Practices

The optimal strategy to transfer and commercialize many genomic inventions is not always apparent at early stages of technology development. As an initial step in these instances, it may be prudent to protect the intellectual property rights to the invention. As definitive commercial pathways unfold, those embodiments of an invention requiring exclusive licensing as an incentive for commercial development of products or services can be distinguished from those that would best be disseminated non-exclusively in the marketplace.