history update forms will provide essential data for outcomes assessment for this population of aging women.

Frequency of Response: Annually. *Affected Public:* Individuals and physicians. *Type of Respondents:* Women, next-of-kin, and physician's office staff. The annual reporting burden is as follows:

ESTIMATE OF ANNUAL HOUR BURDEN

Type of response	Number of respondents	Frequency of response	Average hours per response	Annual hour burden
Observational Study Participants	42,550	1.12	.4155	19,801
Next of Kin[1]	941	1	.083	78
Health Care Providers[1]	8	1	.085	.68
Total	43,499			19,880

[1] Annual burden is placed on health care providers and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

The annualized cost burden to respondents is estimated at $397,617. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Shari Eason Ludlam, Project Officer, Women's Health Initiative Program Office, 6701 Rockledge Drive, 2 Rockledge Centre, Room 9188, MSC 7913, Bethesda, MD 20892–7936, or call non-toll-free number (301) 402–2900 or E-mail your request, including your address to: *ludlams@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 23, 2010.

Michael S. Lauer,

Director, Division of Cardiovascular Science, NHLBI, National Institutes of Health.

Dated: March 24, 2010.

Suzanne Freeman,

Chief, FOIA, NHLBI, National Institutes of Health.

[FR Doc. 2010–7741 Filed 4–5–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cancer Therapy Evaluation Program Intellectual Property Option to Collaborator

AGENCY: National Cancer Institute (NCI), National Institutes of Health (NIH), DHHS.

ACTION: Notice; request for comments.

SUMMARY: The National Cancer Institute, Division of Cancer Treatment and Diagnosis, is seeking comments on a proposed revision to its policy on intellectual property agreements with certain funding recipients, entitled the Cancer Therapy Evaluation Program (CTEP) INTELLECTUAL PROPERTY OPTION. The proposed policy, if finalized, would establish that potential applicants for CTEP funding should include an assurance of agreement with the recommended Intellectual Property Option and Institution Notification if they wish to be considered for funding support to carry out any CTEP-sponsored clinical trial for which CTEP holds the investigational new drug (IND) application.

DATES: Comments must be received by NIH on or before May 6, 2010.

ADDRESSES: The NIH welcomes public comment on the full text of the CTEP IP option, set forth below. Comments should be addressed to: CTEP IP Option Project, *nciipoption@mail.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Jason Vittorio Cristofaro, J.D., PhD, Intellectual Property Advisor, National Cancer Institute/NIH/DHHS, Division of Cancer Treatment and Diagnosis, 31 Center Drive, Room 3A44, Bethesda, MD 20892–2580, telephone 301–594–5318, fax 301–496–0826, e-mail *cristofaroj@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains proprietary "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI CTEP-supported clinical trials under funding agreements. As part of the arrangement with these Collaborators to use their proprietary Agents and to make funding clinical research possible, Collaborators will often require, as a condition of collaboration, that the NCI CTEP funding recipients receiving the Agent ("Institutions") agree to certain conditions, including the willingness to provide notice of and grant options to certain intellectual property rights arising from research involving the Agent under the scope of an NCI CTEP funding agreement.

The current IP option language is silent as to the disposition of intellectual property developed from data and Agent-treated samples. As a result, both Collaborators and Institutions have claimed an ownership interest in inventions generated from these data and materials. This lack of clarity has become a major impediment in NCI CTEP's ability to obtain proprietary Agents from collaborators for use in CTEP-sponsored clinical studies, which has resulted in delays

and threatens the continuing ability of CTEP to provide proprietary Agents to CTEP-funded investigators. The lack of Agents for these clinical studies would jeopardize NCI CTEP's ability to support these research activities. The proposed revised CTEP IP Option and Institution Notification is intended to offer appropriate incentives and assurance for both Collaborators and Institutions to participate in CTEP-sponsored clinical studies.

This proposed policy was developed with input from a variety of sources including the CTEP-sponsored cooperative groups, other CTEP-sponsored investigators performing early clinical trials, industry representatives who partner with CTEP and the Council on Government Relations (COGR).

II. Proposed Revision to CTEP Intellectual Property Option

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") through Cooperative Research and Development Agreements ("CRADAs") and other means, for use in NCI-funded research conducted via extramural funding agreements. As part of the arrangement with these Collaborators to use their Agents and to make the collaborative research possible, NCI CTEP would agree not to provide Agents to Institutions unless they provide Collaborators with the IP Options and Institution Notifications described below. The specific terms of the IP Options depend on the types of inventions that arise out of the NCI CTEP funded research (Section A Inventions, Section B Inventions, or Unauthorized Inventions). NCI CTEP is requesting that applicants include assurances of agreement with the terms of the IP Options and Institutional Notification described below in their funding applications to NCI CTEP.

References to "Institution" mean the funding recipient conducting the research described herein. The Intellectual Property Options (IP Options) and Institution Notification described below will apply to inventions arising from research involving the Agent(s) under the scope of an NCI CTEP funding agreement.

A. The IP Option Described in This Section A Would Apply to Inventions That Use or Incorporate the Agent(s) and That are Conceived or First Actually Reduced to Practice Pursuant to NCI CTEP–Funded Clinical or Non-Clinical Studies Utilizing the Agent(s) ("Section A Inventions")

Institution agrees to grant to Collaborator(s): (i) A royalty-free, worldwide, nonexclusive license for commercial purposes; and (ii) a time limited first option to negotiate an exclusive, or co-exclusive, if applicable, worldwide, royalty bearing license for commercial purposes, including the right to grant sub licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the nonexclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) will notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such Section A Invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution agrees not to offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license, Institution agrees to grant Collaborator a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution retains the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

B. The IP Option Described in This Section B Would Apply to Inventions That Do Not Use or Incorporate the Agent(s) but That Are Conceived or First Actually Reduced To Practice Pursuant to NCI CTEP Clinical or Non-Clinical Studies Utilizing the Agent(s). It Also Applies to Inventions That Are Conceived or First Actually Reduced To Practice Pursuant to NCI CTEP Studies Utilizing Clinical Data or Specimens From Patients Treated With the Agent (Including Specimens Obtained From NCI CTEP-Funded Tissue Banks) ("Section B Inventions")

Institution agrees to grant to Collaborator(s): (i) A paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; (ii) a time-limited first option to negotiate a nonexclusive, exclusive, or co-exclusive, if applicable, world-wide royalty-bearing license for commercial purposes, including the right to grant sub-licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution and (iii) a nonexclusive, royalty-free, world-wide license either to (a.) disclose Section B Inventions to a regulatory authority when seeking marketing authorization of the Agent, or (b.) disclose Section B Inventions on a product insert or other promotional material regarding the Agent after having obtained marketing authorization from a regulatory authority. Collaborator will notify Institution, in writing, of its interest in obtaining an exclusive commercial license to any Section B Invention within one year of Collaborator's receipt of a patent application or eighteen months of receipt of an invention report notifying Collaborator of such Section B Invention(s). In the event that

Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option expires with respect to that Section B Invention, and Institution will be free to dispose of its interests in such Section B Invention in accordance with Institution's policies. If Institution and Collaborator fail to reach agreement within ninety (90) days (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Subject B Invention, then for a period of six (6) months thereafter Institution agrees not to offer to license the Section B Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator will have a period of thirty (30) days in which to accept or reject the offer. Institution retains the right to make and use any Section B Inventions for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so. If Collaborator elects to negotiate an exclusive commercial license to a Section B Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and to give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section B Invention.

Inventions arising more than five years after the release of data on the primary end point of the NCI CTEP clinical trial that generated the clinical data and/or specimens will not be subject to the Section B (ii) IP Option.

C. The IP Option Described in This Section C Would Apply to Inventions Made by Institution's Investigator(s) or Any Other Employees or Agents of Institution, Which Are or May Be Patentable or Otherwise Protectable, as a Result of Research Utilizing the Agent(s) Outside the Scope of the NCI CTEP Funding Agreement (Unauthorized Inventions)

Institution agrees, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to Unauthorized Inventions.

D. Institution Notification

Institution agrees to promptly notify NCI CTEP (*NCICTEPpubs@mail.nih.gov*) and Collaborator(s) in writing of any Section A Inventions, Section B Inventions, and Unauthorized Inventions upon the earlier of: (i) Any submission of any invention disclosure to Institution of a Section A, Section B, or Unauthorized Invention, or (ii) the filing of any patent applications of a Section A, Section B, or Unauthorized Invention. Institution agrees to provide a copy of either the invention disclosure or the patent application to the Collaborator and to NCI CTEP which will treat it in accordance with 37 CFR part 401. These requirements do not replace any applicable reporting requirements under the Bayh-Dole Act, 35 U.S.C. 200–212, and implementing regulations at 37 CFR part 401.

III. Request for Comments

NCI CTEP is seeking comment not only from NCI CTEP funding recipients, but from the full range of academic, not-for-profit, government, and private sector participants in biomedical research and development. Widespread comment and participation by varied stakeholders in the biomedical research and development enterprise is critical if this language is to be effective in guiding the interactions of NIH funding recipients with external Collaborators in CTEP-funded studies.

Dated: March 30, 2010.

Jeffrey Abrams,

Associate Director, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI, National Institutes of Health.

[FR Doc. 2010–7743 Filed 4–5–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0079]

Determination of Regulatory Review Period for Purposes of Patent Extension; TOVIAZ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TOVIAZ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product TOVIAZ (fesoterodine fumarate). TOVIAZ is indicated for treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TOVIAZ (U.S. Patent No. 6,858,650) from Schwarz Pharma AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark