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

Office that this human drug product had undergone a regulatory review period and that the approval of TOVIAZ represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TOVIAZ is 2,395 days. Of this time, 1,445 days occurred during the testing phase of the regulatory review period, while 950 days occurred during the 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*: April 13, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 13, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: March 27, 2006. The applicant claims March 17, 2006, as the date the new drug application (NDA) for TOVIAZ (NDA 22–030) was initially submitted. However, FDA records indicate that NDA 22–030 was submitted on March 27, 2006.

3. *The date the application was approved*: October 31, 2008. FDA has verified the applicant's claim that NDA 22–030 was approved on October 31, 2008.

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 1,155 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 by June 7, 2010. 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 October 4, 2010. 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 should 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: March 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–7679 Filed 4–5–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0400]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for FANAPT 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 FANAPT (iloperidone). FANAPT is indicated for the acute treatment of schizophrenia in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for FANAPT (U.S. Patent No. RE39,198) from Aventis Holdings Inc., 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 2, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of FANAPT represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for FANAPT is 6,552 days. Of this time, 5,964 days occurred during the testing phase of the regulatory review period, while 588 days occurred during the 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*: May 31, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 31, 1991.