FY 2011 reporting year and thereafter, while the current reporting, OMB Approval Number 0985–0008, will be extended to the end of the FY 2010 reporting cycle. The proposed FY 2011 version may be found on the AoA web site link entitled Proposed SPR for Review available at *http://www.aoa.gov/AoARoot/Program_Results/docs/SPR-Draft_form_2010_draft.pdf*.

AoA estimates the burden of this collection of information as follows: 2,828 hours

Dated: April 8, 2010.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2010–8482 Filed 4–13–10; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0180]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adoption of the FDA Food Code by Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's collection of information from local, State, and tribal governmental agencies concerning their adoption of, or plans to adopt, all or portions of the FDA Food Code or its equivalent by regulation, law, or ordinance.

DATES: Submit written or electronic comments on the collection of information by June 14, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adoption of the FDA Food Code by Local, State, and Tribal Governments—42 U.S.C. 243 (a); (OMB Control Number 0910–0448)—Extension

FDA has developed its model Food Code to assist and promote consistent implementation of national food safety regulatory policy among the local, State, and tribal governmental agencies that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243(a)). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service (IHS).

Nationwide adoption of the model FDA Food Code is an important step toward the agency's goal for consistent, scientifically sound, and risk-based food safety standards and practices. A current, comprehensive, and accurate inventory of food code adoptions by States and U.S. territories, local, and tribal governments is necessary to determine the status of up-to-date protection of the U.S. population and to identify areas where assistance to these governments may promote the adoption of regulations based on the FDA Food Code.

This collection effort, which began in 2001, has had remarkable success with 97 percent participation from State and territorial governmental agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. The rulemaking process that local, State, territorial, and tribal governmental agencies must follow to adopt the model FDA Food Code is often a long and complicated process that can extend for several years. For this reason, many agencies have reported that they are still in the rulemaking process to adopt or update their food codes. Thus, FDA believes that extension of OMB approval of the survey is needed in order to keep the current database accurate and up-to-date. The contractor will collect the information electronically and/or telephonically and will be able to provide respondents with previous survey responses already in the database.

Description of Respondents: Respondents to this information collection are States and U.S. territories, local, and tribal governmental agencies.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Food Code Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Respondents	75	4	300	1	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of updates received in the past 3 years. FDA estimates that 75 respondents will provide four quarterly updates each, resulting in an estimated 300 total annual responses. The agency estimates that each quarterly update will take about 1 hour. Of the 75 respondents, those who amend their regulations with changes unrelated to the risk factors and interventions, and those who are not adopting model FDA Food Code provisions, but are incorporating certain Conference for Food Protection recommendations only, will likely need only annual contact.

Dated: April 9, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8510 Filed 4–13–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0413]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AFINITOR 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 AFINITOR (everolimus). AFINITOR is indicated for treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AFINITOR (U.S. Patent No. 5,665,772) from Novartis 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 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 AFINITOR 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 AFINITOR is 4,486 days. Of this time, 4,212 days occurred during the testing phase of the regulatory review period, while 274 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*: December 19, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: June 30, 2008. FDA has verified the applicant's claim that the new drug application (NDA) 22–334 was submitted on June 30, 2008.

3. *The date the application was approved*: March 30, 2009. FDA has verified the applicant's claim that NDA 22–334 was approved on March 30, 2009.

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 1,826 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 14, 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 12, 2010. To meet its burden,