ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 8, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0138. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reclassification Petitions for Medical Devices—21 CFR Section 860.123 (OMB Control Number 0910–0138)—Extension

FDA has responsibility under sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), and (f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes i.e, I, II, and III, to another class. The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a ''Supplemental Data Sheet,'' Form FDA 3427, and a ''Classification Questionnaire,'' Form FDA 3429. Both forms are a series of questions concerning the safety and effectiveness of the device type. Further, the reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use. Thus, the reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements. The reclassification petitions requesting classification from class III to class II or class I, if approved, provides an alternative route to the market in lieu of premarket approval for class III devices or from class I or II, to one or the other class, which may increase requirements.

In the **Federal Register** of December 4, 2008 (73 FR 73938), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

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

Based on the last 3 years, and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff that: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

Dated: March 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4829 Filed 3–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0098]

Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Potential Data Sources for the Sentinel Initiative

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed information collection through a survey designed to identify potential data sources and/or data environments that could participate in the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the postmarket performance of a medical product.

DATES: Submit written or electronic comments on the collection of information by May 8, 2009.

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: Jonna Capezzuto, Office of Information

Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794. To obtain a copy of the draft survey instrument contact Tomeka Arnett on 301–827–1512.

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 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.

Evaluation of Potential Data Sources for the Sentinel Initiative

In September 2005, the Secretary of Health and Human Services (the Secretary) asked FDA to expand its current system for monitoring medical product performance. The Secretary asked FDA to explore the possibility of working in collaboration with multiple healthcare data systems to augment FDA's capability of identifying and evaluating product safety information beyond its existing voluntary reporting systems. Such a step would strengthen FDA's ability, ultimately, to monitor the performance of a product after marketing approval. The Secretary recommended that FDA explore creating a public-private collaboration as a framework for such an effort leveraging increasingly available large, electronic healthcare databases and taking advantage of emerging technologies and building on existing systems and efforts, rather than creating new systems.

In 2006, the Institute of Medicine (IOM) issued a report entitled ''The Future of Drug Safety—Promoting and Protecting the Health of the Public.''[1] Among other suggestions, this IOM report recommended FDA identify ways to access other health-related databases and create a public-private partnership to support safety and efficacy studies.

In 2007, Congress enacted the Food and Drug Administration Amendments Act of 2007[2] (FDAAA). Section 905 of FDAAA calls for the Secretary to develop methods to obtain access to disparate data sources and to establish an active postmarket risk identification and analysis system that links and analyzes healthcare data from multiple sources. The law sets a goal of access to data from 25 million patients by July 1, 2010, and 100 million patients by July 1, 2012. The law also requires FDA to work closely with partners from public, academic, and private entities. FDA views the Sentinel Initiative as a mechanism through which this mandate can be carried out.

Consistent with FDA's mission to protect and promote the public health, FDA is embarking on the Sentinel Initiative to create a national, electronic distributed system, strengthening FDA's ability to monitor the post-market performance of a product. As currently envisioned, the Sentinel Initiative will enable FDA to capitalize on the capabilities of multiple, existing data systems (e.g. electronic health record systems and medical claims databases) to augment the agency's current surveillance capabilities. The proposed system will enable queries of distributed data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Operations will adhere to strict privacy and security safeguards.

The success of this Initiative will depend largely on the content, quality, searchability, and responsiveness of participating data sources and/or data environments. It is essential that FDA understand the strengths and limitations of potential data sources that might be included in the Sentinel Initiative. This survey will be used to collect information from potentially participating data sources and/or environments. The data we are seeking will describe the characteristics of the data available, not personally identifiable information. The findings will help FDA plan for this proposed system and for future work related to the Sentinel Initiative.

This survey will collect information on the scope, content, structure, quality, and timeliness of data; patient population(s), duration of follow up, and capture of care across all settings; availability, experience, and interest of investigators with knowledge of the data in using it for post-market product safety surveillance as well as plans for further data source enhancements; availability, experience, and interest of investigators with knowledge of the data in participating in a distributed data system; and barriers that exist to including each data source in the Sentinel Initiative.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Data Source and/or Environment Survey	250	1	250	24.5	6,125

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

[1] Institute of Medicine, ''The Future of Drug Safety—Promoting and Protecting the Health of the Public,'' September 22, 2006, *http://www.iom.edu/*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

[2] Food and Drug Administration Amendments Act of 2007, Public Law 110–85, was signed into law in September 2007. See Title IX, Section 905.

FDA estimates that approximately 250 respondents will participate in this voluntary survey. These respondents will consist mostly of other Federal agencies, health plan data sources, health information exchanges, large multi-specialty medical groups and academic medical centers, large hospital systems, pharmacies, medical societies, consumer-oriented Web sites, commercial data sets, research networks, lab data, and registries.

Each respondent will extend approximately 24.5 hours to complete 1 survey for a total of 6,125 hours (250 x 1 x 24.5 = 6,125).

Dated: February 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4830 Filed 3–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0164]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALTABAX OINTMENT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ALTABAX OINTMENT 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 human drug product 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 ALTABAX OINTMENT (retapamulin). ALTABAX OINTMENT is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes* in patients aged 9 months or older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALTABAX OINTMENT (U.S. Patent No. RE39,128E) from SmithKline Beecham P.L.C., and SmithKline Beecham Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 28, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ALTABAX OINTMENT 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 ALTABAX OINTMENT is 1,602 days. Of this time, 1,297 days occurred during the testing phase of the regulatory review period, while 305 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*: November 24, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 24, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: June 12, 2006. FDA has verified the applicant's claim that the new drug application (NDA) for ALTABAX OINTMENT (NDA 22–055) was initially submitted on June 12, 2006.

3. *The date the application was approved*: April 12, 2007. FDA has verified the applicant's claim that NDA 22–055 was approved on April 12, 2007.

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 833 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 May 8, 2009. 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 8, 2009. 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.