with this provision is approved under OMB control number 0910–0437.

Respondents to this collection of information are manufacturers of in vitro diagnostic devices.

In the **Federal Register** of September 7, 2005 (70 FR 53231), FDA solicited comments on the collection of information requirements. No comments were received in response to this notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
40	1	40	780	31,200	$5,500

[1]There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours	Total Operating & Maintenance Costs
40	1	40	2,800	112,000	$60,700

[1]There are no capital costs associated with this collection of information.

Based on previous years of experience, with CLIA waiver applications, FDA expects 40 manufacturers to apply for one CLIA waiver per year. The annual reporting burden to respondents is estimated to be 31,200 hours and the recordkeeping burden for respondents is estimated to be 112,00 hours. FDA based the reporting and recordkeeping burden on agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests.

The total operating and maintenance costs associated with the implementation of this draft guidance is estimated to be $66,200. The cost consists of specimen collections for the clinical study (estimated at $23,500); laboratory supplies, reference testing, and study oversight (estimated at $26,700); shipping and office supplies (estimated at $6,000); and educational materials, including quick reference instructions (estimated at $10,000).

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–15693 Filed 9–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0357]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

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 extending OMB approval on the existing reporting and recordkeeping requirements for processors and importers of fish and fishery products.

DATES: Submit written or electronic comments on the collection of information by November 27, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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 Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—21 CFR Part 123 (OMB Control Number 0910–0354)—Extension

FDA regulations in part 123 (21 CFR part 123) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and became effective on December 18, 1997.

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the values for processing times, temperatures, acidity, etc., as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and on the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. Costs were estimated for the collection of HACCP data for each type of recordkeeping activity using a labor cost of $15.00 per hour.

The burden estimate in table 1 of this document includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. The estimate also does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in table 1 account only for information collection and recording requirements attributable to part 123.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section[2]	No. of Respondents	Annual Frequency per Response[3]	Total Annual Responses	Hours per Response[4]	Total Hours
123.6(a),(b), and (c)	275	1	275	16.00	4,400
123.6(c)(5)	5,500	4	22,000	0.30	6,600
123.8(a)(1) and (c)	5,500	1	5,500	4.00	22,000
123.12(a)(2)(ii)	1,100	80	88,000	0.20	17,600
123.6(c)(7)	5,500	280	1,540,000	0.30	462,000
123.7(d)	2,200	4	8800	0.10	880
123.8(d)	5,500	47	258,500	0.10	25,850
123.11(c)	5,500	280	1,540,000	0.10	154,000
123.12(c)	1,100	80	88,000	0.10	8,800
123.12(a)(2)	55	1	55	4.00	220
123.10	275	1	275	24.00	6,600
Total					708,950

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

[2]These estimates include the information collection requirements in the following sections:§ 123.16Smoked Fish—process controls (see § 123.6(b))§ 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b))§ 123.28(c) and (d)—Records—molluscan shellfish (see § 123.6(c)(7))

[3]Based on an estimated 280 working days per year.

[3]Based on an estimated 280 working days per year.

[4]Estimated average time per 8-hour work day unless one-time response.

Dated: September 19, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–15694 Filed 9–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0427]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KETEK 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 that 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 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 KETEK (telithromycin). KETEK is indicated for treatment of acute bacterial exacerbation of chronic bronchitis due to *Streptococcus (S.) pneumoniae*, *Haemophilus (H.) influenzae*, or *Moraxella (M.) catarrhalis*, acute bacterial sinusitis due to *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, or *Staphylococcus aureus*, and community-acquired pneumonia due to *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, *Chlamydophila pneumoniae*, or *Mycoplasma pneumoniae*, for patients 18 years old and above. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for KETEK (U.S. Patent No. 5,635,485) from Aventis S. A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 29, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of KETEK represented the first permitted commercial marketing or use of the product. Shortly 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 KETEK is 2,206 days. Of this time, 713 days occurred during the testing phase of the regulatory review period, while 1,493 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*: March 20, 1998. The applicant claims February 19, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 20, 1998, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: March 1, 2000. The applicant claims February 28, 2000, as the date the new drug application (NDA) for Ketek (NDA 21–144) was initially submitted. However, FDA records indicate that NDA 21–144 was submitted on March 1, 2000.

3. *The date the application was approved*: April 1, 2004. FDA has verified the applicant's claim that NDA 21–144 was approved on April 1, 2004.

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 1,076 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 November 27, 2006. 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 March 26, 2007. 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: September 1, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–15690 Filed 9–25–06; 8:45 am]

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