[3]Based on an estimated 280 working days per year.
[4]Estimated average time per 8-hour workday unless one-time response.

FDA bases this hour burden estimate on its experience with the application of HACCP principles in food processing. Further, the burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. The hour burden of HACCP recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the size of the facility and complexity of the HACCP control scheme (i.e., the number of products and the number of hazards controlled); the daily frequency that control points are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The burden estimate does not include burden hours for activities that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors.

Based on its records, FDA estimates that there are 15,000 processors and 4,100 importers. FDA estimates that 50 processors will undertake the initial preparation of a hazard analysis and HAACP plan (§ 123.6(a),(b), and (c)). FDA estimates the burden for the initial preparation of a hazard analysis and HAACP plan to be 16 hours per processor for a total burden of 800 hours. FDA estimates that all processors (15,000 processors) will undertake and keep records of 4 corrective action plans (§ 123.6(c)(5)) for a total of 60,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 18,000 hours.

FDA estimates that all processors (15,000 processors) will annually reassess their hazard analysis and HACCP plan (§ 123.8(a)(1) and (c)). FDA estimates the burden for the reassessment of the hazard analysis and HAACP plan to be 4 hours per processor for a total burden of 60,000 hours.

FDA estimates that all importers (4,100 importers) will take affirmative steps to verify compliance of imports and prepare 80 records of their verification activities (§ 123.12(a)(2)(ii)) for a total of 328,000 records. FDA estimates the burden for the preparation of each record to be 0.20 hours for a total burden of 65,600 hours.

FDA estimates that all processors (15,000 processors) will document the monitoring of critical control points (§ 123.6(c)(7)) at 280 records per processor for a total of 4,200,000 records. FDA estimates the burden for the preparation of each record to be 0.30 hours for a total burden of 1,260,000 hours.

FDA estimates that 40 percent of all processors (6,000 processors) will maintain records of any corrective actions taken due to a deviation from a critical limit (§ 123.7(d)) at 4 records per processor for a total of 24,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 2,400 hours.

FDA estimates that all processors (15,000 processors) will maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing (§ 123.8(d)) at 47 records per processor for a total of 705,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 70,500 hours.

FDA estimates that all processors (15,000 processors) will maintain sanitation control records (§ 123.11(c)) at 280 records per processor for a total of 4,200,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 420,000 hours.

FDA estimates that all importers (4,100 importers) will 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 (§ 123.12(c)). FDA estimates that 80 records will be prepared per importer for a total of 328,000 records. FDA estimates the burden for the preparation of each record to be 0.10 hours for a total burden of 32,800 hours.

FDA estimates that 1 percent of all importers (41 importers) will require new written verification procedures to verify compliance of imports (§ 123.12(a)(2)). FDA estimates the burden for preparing the new procedures to be 4 hours per importer for a total burden of 164 hours.

Dated: June 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–14817 Filed 6–17–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; National Institute of Diabetes and Digestive and Kidney Diseases Information Clearinghouses Customer Satisfaction Survey

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institutes of Health (NIH), is giving public notice that the agency proposes to request reinstatement of an information collection activity for which approval expired on February 28, 2010.

Proposed Collection

Title: NIDDK Information Clearinghouses Customer Satisfaction Survey. *Type of Information Requested:* Reinstatement, with change, of a previously approved collection for which approval has expired. The OMB control number 0925–0480 expired on February 28, 2010. *Need and Use of Information Collection:* NIDDK is conducting a survey to assess the efficiency and effectiveness of services provided by NIDDK's three clearinghouses: The National Diabetes Information Clearinghouse (NDIC); the National Digestive Diseases Information Clearinghouse (NDDIC); and the National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). The survey responds to Executive Order 12821, "Setting Customer Service Standards," which requires agencies and departments to identify and survey their "customers to determine the kind and quality of service they want and their level of satisfaction with existing services." *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; business and for profit organizations; not-for-profit agencies. *Type of Respondents:* Physicians, health care professionals, patients, family and friends of patients.

The annual reporting burden is as follows: Estimated number of respondents: 7,079; estimated number of responses per respondent: 1; estimated average burden hours per response: 0.025; and estimated total annual burden hours requested: 177. The

annualized cost to respondents is estimated at $3,793.00. There are no capital costs to report. There are no operating or maintenance costs to report.

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 reports and instrument, contact Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852 or e-mail your request, including your address to: *KranzfelderK@mail.nih.gov.* To request more information on the proposed project or to obtain a copy of the data collection reports and instrument, contact Kathy Kranzfelder, Director, NIDDK Office of Communications and Public Liaison, Building 31, Room 9A06, MSC2560, Bethesda, MD 20852. You may also submit comment and data by electronic mail (e-mail) at *KranzfelderK@mail.nih.gov.*

Dated: June 14, 2010.

Lynell Nelson,

NIDDK Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–14793 Filed 6–17–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–E–0268 and FDA–2008–E–0267]

Determination of Regulatory Review Period for Purposes of Patent Extension; BYSTOLIC; U.S. Patent Nos. 5,759,580 and 6,545,040

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. 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.

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 BYSTOLIC (nebivolol hydrochloride). BYSTOLIC is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for BYSTOLIC (U.S. Patent Nos. 5,759,580 and 6,545,040) from Forest Laboratories, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated June 10, 2008, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BYSTOLIC 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 BYSTOLIC is 6,790 days. Of this time, 5,463 days occurred during the testing phase and 1,327 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (U.S.C. 355 (i)) involving this drug product became effective*: May 17, 1989. The applicant claims July 6, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND originally became effective on May 17, 1989, which was 30 days after FDA receipt of the original IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: April 30, 2004. The applicant claims April 29, 2004, as the date the new drug application (NDA) for BYSTOLIC (NDA 21–742) was initially submitted. However, FDA records indicate that NDA 21–742 was submitted on April 30, 2004.

3. The date the application was approved: December 17, 2007. FDA has verified the applicant's claim that NDA 21–742 was approved on December 17, 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 applications for patent extension, this applicant seeks 1,828 days of patent term extension for U.S. Patent No. 5,759,580 and 619 days of patent term extension for U.S. Patent No. 6,545,040.

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 August 17, 2010. Furthermore, any interested person may petition FDA for a determination