DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0136]

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 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 16, 2003.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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: (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 (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 jurisdictions 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)) and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs relative to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). 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 towards 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 agencies. FDA contracted with the Association of Food and Drug Officials (AFDO) to conduct the initial survey using the OMB approved survey form. Contacts were made by telephone and e-mail to determine the Food Code status in their jurisdiction(s). Follow up contacts by telephone and e-mail to minimize the burden on respondents were made to clarify responses.

The rulemaking process that local, State, territorial, and tribal governments must follow to adopt the Food Code is often a long and complicated process that can extend 2 or more years. For this reason, many agencies reported in the initial survey that they were still in the rulemaking process to adopt or update their food codes for the years 2004 and 2005 or beyond. Thus, FDA believes that further implementation of the initial survey is needed to cover this additional rulemaking in order to keep the current database accurate and up-to-date. Based on experience gained in the past 3 years from the initial survey, FDA has developed a more condensed follow up survey to further minimize the burden requirements on respondent agencies. For example, FDA now knows if responding agencies have adopted a new code since 1993, the types of establishments regulated by those codes, the populations of the jurisdiction covered, and the status of local health agencies in the States. This information will not be collected again. We have reduced the number of questions from 16 to 5. Collection(s) of information will be electronically and/or telephonically obtained thus, providing respondents with data already in the database to further the ease of response and lower the burden.

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
Food Code Survey	150	4	600	1	600

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

Experience in the initial survey has more clearly identified the respondents for updating the information in the database. For example, FDA will obtain information from IHS, relative to the tribal nations' adoption of the Food Code that IHS maintains, using the information categories in the revised follow up survey form for which this extension is requested. Seventy-three State and territorial agencies were identified as respondents for Food Code adoption and it appears that initially, only 30 local agencies in cities of 500,000 or more will need to be contacted because most local jurisdictions are under State requirements. This further reduces the total burden on respondents. Quarterly updates from respondents under active rulemaking will be requested by AFDO to keep the database current and accurate. Respondents that have concluded rulemaking will likely need only annual contact. Estimated response time is about 1 hour or less because most reporting will be done telephonically or electronically.

Dated: April 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02E–0021]

Determination of Regulatory Review Period for Purposes of Patent Extension; HYPERION LTK SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HYPERION LTK SYSTEM 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 medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (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: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device HYPERION LTK SYSTEM. HYPERION LTK SYSTEM is indicated for temporary reduction of hyperopia in patients with +0.75 to +2.5 diopters of manifest refraction spherical equivalent at the spectacle plane (with cylinder less than or equal to +0.75 diopters) who are 40 years of age or older with documented stability of refraction for the prior 6 months, as demonstrated by a change of less than or equal to 0.50D in spherical and cylindrical components of the manifest refraction. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HYPERION LTK SYSTEM (U.S. Patent No. 4,976,709) from Sunrise Technologies International, 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 October 31, 2002, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of HYPERION LTK SYSTEM 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 HYPERION LTK SYSTEM is 3,047 days. Of this time, 2,806 days occurred during the testing phase of the regulatory review period, while 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: February 28, 1992. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective February 28, 1992.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: November 3, 1999. The applicant claims November 1, 1999, as the date the premarket approval application (PMA) for HYPERION LTK SYSTEM (PMA P990078) was initially submitted. However, FDA records