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.

[FR Doc. 03–9533 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

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

indicate that PMA P990078 was submitted on November 3, 1999.

3. *The date the application was approved*: June 30, 2000. FDA has verified the applicant's claim that PMA P990078 was approved on June 30, 2000.

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 1,644 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 16, 2003. 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 14, 2003. 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 Dockets Management Branch (see **ADDRESSES**). 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 31, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–9535 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 23, 2003, from 8:30 a.m. to 3:30 p.m.

Location: Gaithersburg Marriott, Salons A, B and C, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, ext. 127, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an intraocular lens for primary implantation in the capsular bag for the correction of aphakia in an adult in whom a cataractous lens has been removed and who may benefit from improved near, intermediate and distance vision without spectacles. Background information for the day's topic, including the attendee list, agenda, and questions for the committee, will be available to the public one business day before the meeting, on the Internet at http://www.fda.gov/cdrh/panel/index.html. Material will be posted on May 22, 2003.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 16, 2003. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and for 30 minutes near the end of the committee deliberations on the PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 16, 2003 and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9386 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting; Correction

AGENCY: Food and Drug Adminstration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 3, 2003 (68 FR 16292). The notice announced a meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science, which was scheduled for April 22–23, 2003. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–8011, appearing on page 16292 in the **Federal Register** of Thursday, April 3, 2003, the following correction is made:

1. On page 16292, in the first column, in the ''*Location*'' section, ''5600'' is corrected to read ''5630''.

Dated: April 10, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9384 Filed 4–16–03; 8:45 am]

BILLING CODE 4160–01–S