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 Commissioner 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 Synvisc Hylan G–F 20 (5,143,724)®. Synvisc Hylan G–F 20 (5,143,724)® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (e.g., acetaminophen). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Synvisc Hylan G–F 20 (5,143,724)® (U.S. Patent No. 5,143,724) from Biomatrix, 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 December 11, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Synvisc Hylan G–F 20 (5,143,724)® 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 Synvisc Hylan G–F 20 (5,143,724)® is 2,949 days. Of this time, 1,783 days occurred during the testing phase of the regulatory review period, while 1,166 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:* July 14, 1989. 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 July 14, 1989.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* May 31, 1994. FDA has verified the applicant's claim that the premarket approval application (PMA) for Synvisc Hylan G–F 20 (5,143,724)® (PMA P940015) was initially submitted May 31, 1994.

3. *The date the application was approved:* August 8, 1997. FDA has verified the applicant's claim that PMA P940015 was approved on August 8, 1997.

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 396 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by March 12, 2001. 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 July 9, 2001. 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. Three copies of any 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: December 20, 2000.

Jane A. Axelrad,

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

[FR Doc. 01–683 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

The 2001 FDA Science Forum—Science Across the Boundaries

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Office of Science is announcing the following meeting entitled ''The 2001 FDA Science Forum—Science Across the Boundaries.'' The science forum is FDA's key scientific meeting that seeks to communicate and promote scientific issues relating to scientific development and associated regulatory concerns. The 2001 forum is designed to bring FDA scientists together with representatives from industry, academia, government agencies, consumers groups, international constituents, and the public to explore science across the boundaries of these groups.

Date and Time: The science forum will be held on Thursday, February 15, 2001, from 8:30 a.m. to 5 p.m., and Friday, February 16, 2001, from 8:30 a.m. to 4:30 p.m.

Location: Washington Convention Center, 900 Ninth St. NW., Washington, DC 20001.

Contact: AOAC International, Fulfillment Department, 301–924–7077, e-mail: fulfillment@aoac.org, or Donna L. Mentch, Food and Drug Administration, Office of Science (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, e-mail: dmentch@oc.fda.gov.

Registration: Attendees may register from 7 a.m. to 5 p.m. on February 15, 2001, and from 8 a.m. to 1 p.m. on February 16, 2001. Registration and program information are also available at http://www.aoac.org/meetings1/fdascienceforum.html. Attendance will be limited; therefore, interested parties are encouraged to register early.

SUPPLEMENTARY INFORMATION: Speakers and panelists will address emerging issues in privacy and confidentiality, modeling and simulation, leveraging and partnerships across FDA boundaries, and laboratory accreditation.

A poster session featuring all areas of FDA regulatory science will be presented to provide an opportunity for interested scientists to engage in information exchange with FDA scientists. The session topics to be discussed include the following:

1. Health Informational Privacy: Individual Right or Public Good;
2. Modeling and Simulation for Transdisciplinary Collaboration: The Boeing 777 Story;
3. Perspectives on Confidentiality, Conflict of Interest, and Privacy Issues Surrounding the Advancing Science of Gene Therapy;
4. Modeling and Simulation Across Pharmaceutical Boundaries;
5. Privacy and Confidentiality Issues in Registries and in Outcomes/Epidemiology Research;
6. Modeling and Simulation in Clinical Product Development for the New Millennium;
7. Scientific, Privacy, and Ethical Issues Surrounding the Advancing Science Genetic Predisposition for Breast Cancer;
8. Modeling and Simulation: The Path to the Future;
9. Scientific Training Outside the Boundaries;
10. Next Generation Leveraging;
11. Public Health Preparedness for Bioterrorism: Why Leveraging is Essential;
12. Partnering Across the Boundaries;
13. Global Partnering: Mutual Recognition Agreements and How They Affect You.

The science forum is cosponsored by FDA's Office of Science Coordination and Communication, AOAC International, and FDA's Chapter of Sigma Xi, The Scientific Research Society.

If you need special accommodations due to a disability, please contact the AOAC International at least 3 weeks in advance.

Dated: January 4, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–629 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Obstetrics and Gynecology 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Obstetrics and Gynecology 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 January 29, 2001, 8 a.m. to 5 p.m.

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

Contact Person: Elisa D. Harvey, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12524. 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 for an endometrial ablation device.

Procedure: On January 29, 2001, from 9 a.m. to 5 p.m., the meeting is open to the public. 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 January 19, 2001. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 3:30 p.m. and 4 p.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before January 19, 2001, 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.

Closed Committee Deliberations: On January 29, 2001, from 8 a.m. to 9 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future device issues.

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

Dated: December 28, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–682 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10021]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Request: New collection;

Title of Information Collection: Collection of data on Hospital Outpatient Encounters from Medicare+Choice Programs;

Form Number: HCFA–10021 (OMB approval #: 0938–NEW);

Use: HCFA requires hospital outpatient encounter data from Medicare+Choice organizations to develop and implement a risk adjustment payment methodology as required by the Balance Budget Act of 1997;

Frequency: Monthly;

Affected Public: Business or other for-profit, Not-for-profit institutions;

Number of Respondents: 300;

Total Annual Responses: 12,600;

Total Annual Hours Requested: 60,375.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web