Commissioner 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.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 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 (5,099,013)®. Synvisc Hylan G–F 20 (5,099,013)® is indicated for the treatment of pain in osteoarthritis 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 (5,099,013)® (U.S. Patent No. 5,099,013) 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 (5,099,013)® 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 (5,099,013)® 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 (5,099,013)® (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 13, 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 11, 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. 01–974 Filed 1–11–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Anti-Infective Drugs Advisory Committee. This meeting was announced in the **Federal Register** of December 27, 2000 (65 FR 81874). The amendment is being made to cancel the entire session on January 29, 2001. This meeting will be open to the public. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 27, 2000 (65 FR 81874), FDA announced that a meeting of the Anti-Infective Drugs Advisory Committee would be held on January 29 and 30, 2001. On page 81874, beginning in the first column, the *Date and Time*, *Location*, *Agenda*, and *Procedure* portions of this meeting are amended to read as follows:

Date and Time: The meeting will be held on January 30, 2001, 8 a.m. to 6 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Ave., Gaithersburg, MD.

Agenda: The committee will consider the safety and efficacy of a new drug application (NDA) 50–755, Augmentin ES™ (amoxicillin/clavulanate) 90 milligrams per kilograms per day, SmithKline Beecham Pharmaceuticals, for the treatment of pediatric patients with acute otitis media due to penicillin resistant *Streptococcus pneumoniae*.

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 January 22, 2001. Oral presentations from the public will be scheduled between approximately 2:45 p.m. to 3:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 22, 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.

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

Dated: January 5, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–1056 Filed 1–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–26]

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: Extension of a currently approved collection; Title of Information Collection: Clinical Laboratory Improvement Amendments (CLIA) and the ICRs contained in the supporting regulations in 42 CFR 493.1–.2001; Form Number: HCFA–R–26 (OMB approval #: 0938–0612); Use: The ICRs referenced in 42 CFR part 493 outline the requirements necessary to determine an entity's compliance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by HHS; Frequency:Other: As needed; Affected Public; Business or other for-profit, Not-for-profit institutions, Federal government, State, local or tribal gov't; Number of Respondents: 149,700; total Annual Responses: 700,650; Total Annual Hours Requested: 10,230,714.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1069 Filed 1–11–01; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Docket Identifier: HCFA–1500]

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: Extension of a currently approved collection; Title of Information Collection; Medicare/Medicaid Health Insurance Common Claim Form, Instructions, and Supporting Regulations: 42 CFR 414.40, 424.32, 424.44; Form Number: NCFA–1500, HCFA–1490U, HCFA–1490S (OMB approval #: 0938–0008); Use: This form is a standardized form for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. In addition, it reduces cost and administrative burdens associated with claims since only one coding system is used and maintanined; Frequency: On occasion; Affected Public: Business or other for-profit, Not-for-profit institutions; Number of Respondents: 1,321,417; Total Annual Responses: 1,321,417; Total Annual Hours Requested: 44,189,007.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports