verified the applicant's claim that the new drug application (NDA) for KEPPRA (NDA 21–035) was initially submitted on February 1, 1999.

3. *The date the application was approved*: November 30, 1999. FDA has verified the applicant's claim that NDA 21–035 was approved on November 30, 1999.

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 1,155 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by March 26, 2002. 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 24, 2002. 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 (address above) in three copies (except that individuals may submit single copies) and 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: September 28, 2001.

Jane A. Axelrad,

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

[FR Doc. 02–1927 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs 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: Anti-Infective Drugs 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 February 19, 2002, from 8 a.m. to 5:30 p.m. and on February 20, 2002, from 8 a.m. to 4 p.m.

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

Contact: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@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.

Agenda: On February 19, 2002, the committee will hear presentations on the proposed approach for selection of delta in noninferiority (equivalence) clinical trials. The impact of this approach on studies of anti-infective drug products will be considered, with a focus on acute exacerbation of chronic bronchitis and hospital-acquired-pneumonia. On February 20, 2002, the committee will discuss approaches to the development of antimicrobial agents for the treatment of resistant pathogens.

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 February 11, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 11, 2002, 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 16, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–1814 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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: Oncologic Drugs 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 February 27, 2002, from 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Trial design considerations and appropriate patient populations for studies of investigational agents for adjuvant therapy of melanoma given the availability of an approved agent for this indication; and (2) the appropriate study design and control for the proposed phase 3 trial of investigational new drug (IND) 2885, MELACINE (melanoma vaccine), Corixa Corp., for adjuvant treatment of melanoma.

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 February 20, 2002. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1:15 p.m. and 1:45 p.m. Time allotted for each

presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 20, 2002, 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. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by February 20, 2002, to address issues specific to the topic before the committee.

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

Dated: January 18, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–1924 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Grantee Reporting Requirements for the Rural Health Network Development Grant Program (OMB No. 0915–0218)—Revision

This is a request for revision of the reporting requirements for the Rural Health Network Development Grant Program authorized by section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996 (Pub. L. 104–229).

The purpose of the program is to assist in the development of integrated networks of health care providers in rural communities. Grantee networks work to strengthen the health care delivery system in their service areas thereby improving access to, restraining the cost of, and improving the quality of essential health care services for rural residents. Grantees submit annual reports that provide information on progress toward goals and objectives of the network, specific network activities, and certain financial data related to the grant budget.

The information is used to evaluate progress on the grants, to identify grantees in need of technical assistance, and to identify best practices in the development of rural health networks. The information is also used to evaluate the impact of networks on access of care and quality of care. To minimize the burden on grantees, the reports will be submitted electronically. The estimated burden is as follows:

HRSA form	Number of responses	Responses per respondent	Total reponses	Hours per responses	Total burden hours
Tracking	45	1	45	1.5	67.5

Written comments and recommendations concerning the proposed information collection should be sent within 60 days of this notice to: Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Dated: January 18, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–1850 Filed 1–24–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Healthy Schools, Healthy Communities User/Visit Surveys—NEW

The Bureau of Primary Health Care of HRSA is planning to conduct User/Visit Surveys of the Healthy Schools, Healthy Communities (HSHC) Program. The purpose of these surveys is to obtain nationally representative data about the patients of HSHC health centers and the services provided to them. The study consists of two parts. One is the User Survey, which involves interviewing HSHC patients or their parents about the patients' health and health care. The second is the Visit Survey, in which patient visit data will be collected from medical records in order to find out what health services are being used by