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