IND effective date was December 23, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 505(b) of the act*: September 28, 1999. FDA has verified the applicant's claim that the product license application (BLA) for TNKase (BLA 99–0903) was initially submitted on September 28, 1999.

3. *The date the application was approved*: June 2, 2000. FDA has verified the applicant's claim that BLA 99–0903 was approved on June 2, 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 853 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 comments and ask for a redetermination by November 26, 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 February 26, 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. 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: September 5, 2001.

Jane A. Axelrad,

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

[FR Doc. 01–24126 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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: Biological Response Modifiers 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 October 24, 2001, from 9 a.m. to 3 p.m., on October 25, 2001, from 8 a.m. to 6 p.m., and on October 26, 2001, from 8 a.m. to 3 p.m.

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

Contact: Gail Dapolito or Rosanna L. Harvey (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 24, 2001, the committee will meet to discuss long-term followup of participants in gene transfer clinical trials. On October 25, 2001, the committee will discuss vector design, manufacture, and preclinical studies of lentivirus vectors in gene transfer clinical trials. On October 26, 2001, the committee will discuss development of a lentivirus vector gene transfer product for people with human immunodeficiency virus (HIV).

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 October 18, 2001. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. on October 24, 2001, between approximately 2:45 p.m. and 3 p.m. on October 25, 2001, and between approximately 11:15 a.m. and 11:30 a.m. on October 26, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 18, 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: September 21, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–24158 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology 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: Microbiology 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 October 11, 2001, from 9:30 a.m. to 6:30 p.m., and October 12, 2001, from 8 a.m. to 5 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, ext. 111, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 11, 2001, the committee will discuss, make recommendations, and vote on a premarket approval application for an in vitro diagnostic device for the determination of endotoxin activity in human whole blood samples. On the same day, the committee will provide advice and recommendations on a