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

premarket notification submission for an in vitro diagnostic device for detecting and measuring urinary tract infection by semiquantitative analysis of volatile compounds released from a urine sample.

On October 12, 2001, the committee will discuss, make recommendations, and vote on a premarket approval application for an in vitro diagnostic device for measuring the release of gamma-interferon from sensitized lymphocytes in purified protein derivative (PPD)-stimulated whole blood, as an aid in the diagnosis of latent tuberculosis infection. It is intended to aid in the evaluation of individuals who are suspected of having *Mycobacterium tuberculosis* infection or disease, have close contact with infected individuals, or originate from an area where tuberculosis is prevalent.

Background information for each day's topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the October 11, 2001, session will be posted on October 10, 2001; material for the October 12, 2001, session will be posted on October 11, 2001.

Procedure: On October 11, 2001, from 9:30 a.m. to 6:30 p.m., and on October 12, 2001, from 8:45 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 September 26, 2001. Oral presentations from the public will be scheduled on October 11, 2001, between approximately 11 a.m. and 11:45 a.m. and 5:30 p.m. and 6 p.m. and on October 12, 2001, between approximately 11 a.m. and 12 noon. and 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 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 October 12, 2001, from 8 a.m. to 8:45 a.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Dated: September 20, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–24159 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

Draft ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products;'' Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA) previously requested that comments on the draft entitled ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products'' dated August 2001 be submitted by September 28, 2001, to ensure their adequate consideration in preparation of the final document (66 FR 45683, August 29, 2001). The agency has determined that it will have adequate time to consider, in preparation of the final guidance, comments received by October 28, 2001. FDA is taking this action in response to a request that the agency allow interested parties additional time to review and to submit comments.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by October 28, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 29, 2001 (66 FR 45683), FDA published a notice announcing the availability of a draft guidance document entitled ''Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products.'' The draft guidance document provides comprehensive current recommendations to all registered blood and plasma establishments for deferral of donors with possible exposure to the agent of vCJD. The agency asked interested persons to submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 28, 2001.

On September 19, 2001, a comment from America's Blood Centers was submitted to the docket requesting that FDA consider comments received after September 28, 2001. The comment stated that blood establishment obligations related to the recent terrorist attack has delayed the review of the guidance by a number of blood establishments. The agency has determined that it will have adequate time to consider comments received by October 28, 2001.

II. Comments

Interested persons should submit to the Dockets Management Branch (address above) written or electronic comments regarding the draft guidance document by October 28, 2001, to