Response Survey, with two more in development. FDA is now seeking OMB clearance to continue collecting this information. Participation in these surveys has been, and will continue to be, voluntary. This request covers Rapid Response Surveys for general type medical facilities and specialized medical facilities (those known for cardiac surgery, obstetric/gynecological services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA currently uses the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 rapid response surveys per year with a sample of between 50 and 200 respondents per survey.

FDA originally estimated the burden of this collection to be 2 hours per survey. However, FDA is revising the estimated burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency of Respondent	Total Annual Responses	Hours per Responses	Total Hours
200	10 (maximum)	2,000	.5	1,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency of respondent was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times— depending on the medical device under evaluation. Based on the questions developed for the one survey that has been conducted, and for the two under development, it is estimated, given the expected type of issues that will be addressed by the surveys, that at a maximum it will take 30 minutes for a respondent to gather the requested information and fill in the answers.

Dated: September 21, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24163 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0098]

Determination of Regulatory Review Period for Purposes of Patent Extension; TNKase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TNKase and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human biological product.

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. Submit electronic comments to http://www.fda.gov/dockets.ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. 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 (for example, 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 human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product TNKase (tenecteplase). TNKase is indicated for reduction of mortality associated with acute myocardial infarction (AMI). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TNKase (U.S. Patent No. 5,385,732) from Genetech, 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 May 11, 2001, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of TNKase 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 TNKase is 1,990 days. Of this time, 1,741 days occurred during the testing phase of the regulatory review period, while 249 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: December 23, 1994. The applicant claims February 22, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the

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