(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 16, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1589 Filed 1–23–03; 8:45 am]

BILLING CODE 4121–PN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3113–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 12, 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (the Committee). The Committee provides advice and recommendations to us about clinical issues. Among other things, the Committee advises us on whether adequate evidence exists to determine whether specific medical items and services are reasonable and necessary under Medicare law. The Committee will discuss and make recommendations concerning the quality of the evidence and related issues for the use of a left ventricular assist device as ''destination'' (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Notice of this action is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)).

DATES: *The Meeting:* The public meeting announced will be held on Wednesday, March 12, 2003 from 7:30 a.m. until 3:30 p.m., E.S.T.

Deadline for Presentations and Comments: Interested persons may present data, information, or views orally or in writing, on issues pending before the committee. Written presentations and comments must be submitted to the Executive Secretary by February 20, 2003, 5 p.m., E.S.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by February 26, 2003 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: *The Meeting:* The meeting will be held at the Baltimore Convention Center, Room 338–339, One West Pratt Street, Baltimore, MD 21201.

Presentations and Comments: Submit formal presentations and written comments to Kimberly Long, Executive Secretary, by telephone at 410–786–5702 or by e-mail at *klong@cms.hhs.gov;* Office of Clinical Standards and Quality; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mail Stop C1–09–06; Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *www.cms.gov/coverage.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.

FOR FURTHER INFORMATION CONTACT: Kimberly Long, Executive Secretary, by telephone at (410) 786–5702 or by e-mail at *klong@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (the Committee), which provides advice and recommendations to us about clinical issues. A revised charter was signed by the Secretary on November 22, 2002 (67 FR 79124). This notice announces the following public meeting of the Committee.

Meeting Topic

The Committee will discuss the evidence, hear presentations and public comment, and make recommendations regarding the use of a left ventricular assist device as ''destination'' (permanent) therapy in end-stage heart failure patients who are not eligible for a heart transplant. Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage.*

Procedure and Agenda

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section, and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Panel member before offering your public comments. We will request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2003.

Robert A. Streimer,

Acting Director, Office of Clinical Standards and, Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 03–1588 Filed 1–23–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E–5112]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for NOVOSEVEN 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 which 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 V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 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 NOVOSEVEN (rhFVIIa). NOVOSEVEN is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NOVOSEVEN (U.S. Patent No. 4,784,950) from ZymoGenetics, 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 October 4, 2000, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of NOVOSEVEN 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 NOVOSEVEN is 3,954 days. Of this time, 2,904 days occurred during the testing phase of the regulatory review period, while 1,050 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 (21 U.S.C. 355(i)) became effective*: May 29, 1988. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 1988.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: May 10, 1996. FDA has verified the applicant's claim that the product license application (PLA) for NOVOSEVEN (PLA 96–0597) was initially submitted on May 10, 1996.

3. *The date the application was approved*: March 25, 1999. FDA has verified the applicant's claim that PLA 96–0597 was approved on March 25, 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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 25, 2003. 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 23, 2003. 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: December 19, 2002.

Jane A. Axelrad,

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

[FR Doc. 03–1567 Filed 1–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies 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: Transmissible Spongiform Encephalopathies 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 20, 2003; 8 a.m. to 5:30 p.m.

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

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1449, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 20, 2003, the committee will listen to updates on: Implementation of the variant Creutzfeldt-Jakob Disease (vCJD)