**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)

guidance (''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''; this guidance can be accessed at http://www.fda.gov/cber/guidelines.htm) and its affect on blood supply, and an update on bovine spongiform encephalopathy epidemiology and food chain controls. The committee will then discuss consideration of labeling claims for transmissible spongiform encephalopathy (TSE) agent clearance in plasma derivatives.

*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 13, 2003. Oral presentations from the public will be scheduled between approximately 10:10 a.m. to 10:30 a.m. and between approximately 3 p.m. to 3:40 p.m. on February 20, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 13, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

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

Dated: January 14, 2003.

**Linda Arey Skladany,**

*Associate Commissioner for External Relations.*

[FR Doc. 03–1566 Filed 1–23–03; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information should have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

**Proposed Project: The National Sample Survey of Registered Nurses 2004 (OMB No. 0915–0192)—Revision**

The National Sample Survey of Registered Nurses (NSSRN) is carried out to assist in fulfilling two Congressional mandates. Section 792 of the Public Health Service Act (42 U.S.C. 295k), calls for the collection and analysis of data on health professions. Section 806 (f) of the Public Health Service Act (42 U.S.C. 296e) requires that discipline specific workforce information and analytical activities are carried out as part of the advanced nursing education, workforce diversity, and basic nursing education and practice programs.

Government agencies, legislative bodies and health professionals used data from previous national sample surveys of registered nurses to inform workforce policies. The information from this survey will continue to serve policy makers, and other consumers. Furthermore data collected in this survey will assist in determining the impact that changes in the health care system is having on employment status of registered nurses (RNs), the setting in which they are employed and the proportion of RNs who are employed full time and part time in nursing. The data will also indicate the number of RNs who are employed in jobs unrelated to nursing.

The proposed survey design for the 2004 NSSRN follows that of the previous seven surveys. A probability sample is selected from a sampling frame compiled from files provided by the State Boards of Nursing in the 50 States and the District of Columbia. These files constitute a multiple sampling frame of all RNs licensed in the 50 States and the District of Columbia. Sampling rates are set for each State based on considerations of statistical precision of the estimates and the costs involved in obtaining reliable national and State level estimates.

Each sampled nurse will be asked to complete a self-administered questionnaire, which includes items on educational background, duties, employment status and setting, geographic mobility, and income.

Estimated burden is as follows:

| | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Questionnaires | 39,360 | 1 | 39,360 | .33 | 12,989 |