2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: November 13, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for CYMBALTA (NDA 21–427) was initially submitted on November 13, 2001.

3. *The date the application was approved*: August 3, 2004. FDA has verified the applicant's claim that NDA 21–427 was approved on August 3, 2004.

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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by October 2, 2006. 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 January 30, 2007. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–12574 Filed 8–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance 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: National Mammography Quality Assurance 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 September 28, 2006, from 10 a.m. to 6 p.m., and on September 29, 2006, from 8 a.m. to 1 p.m.

Location: Atrium Court Hotel, Remington 1 and 2, Three Research Ct., Rockville, MD.

Contact Person: Nancy Wynne, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3284, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) Amendments to the current regulations, and (2) all guidance documents issued since the last meeting. The committee will also receive updates on recently approved alternative standards and the radiological health program. MQSA regulations and guidance documents are available to the public on the Internet at *http://www.fda.gov/cdrh/mammography*.

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 on or before August 29, 2006. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. on September 28, 2006, and between approximately 8:30 a.m. and 9:30 a.m. on September 29, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before August 29, 2006.

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 Shirley Meeks, Conference Management Staff, at 301–827–7292, 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: July 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12569 Filed 8–2–06; 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 September 18, 2006, from 8 a.m. to 4:30 p.m. and September 19, 2006, from 8 a.m. to 1 p.m.

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

Contact Person: William Freas or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71),

Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512392. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18, 2006, the committee will hear updates on the following topics: United States and worldwide bovine spongiform encephalopathies (BSE); variant Creutzfeldt-Jakob disease (vCJD) epidemiology and transfusion-transmission; blood and plasma donor deferral for transfusion in France since 1980 guidance; FDA's current assessment and plans regarding the potential exposure to vCJD from an investigational product, FXI, that was manufactured from UK donor plasma; and a summary of World Heath Organization Consultation on distribution of infectivity in tissues of animals and humans with transmissible spongiform encephalopathies. The committee will then discuss experimental clearance of transmissible spongiform encephalopathy infectivity in plasma-derived Factor VIII products. In the afternoon, the committee will discuss FDA's risk assessment for potential exposure to vCJD from human plasma-derived antihemophilic factor (FVIII) products and potential responses. On September 19, 2006, the committee will discuss possible criteria for approval of donor screening tests for vCJD.

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 on or before September 6, 2006. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. and 2:30 p.m. and 3 p.m. on September 18, 2006, and between approximately 10:15 a.m. and 11:45 a.m. on September 19, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before September 11, 2006.

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 Rosanna Harvey 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: July 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12567 Filed 8–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD17–06–001]

Implementation of Sector Anchorage

AGENCY: Coast Guard, DHS.

ACTION: Notice of organizational change.

SUMMARY: The Coast Guard announces the stand-up of Sector Anchorage. The creation of Sector Anchorage is an internal reorganization that combines Marine Safety Office Anchorage with all prior subordinate units in addition to USCGC LONG ISLAND, USCGC MUSTANG, USCGC ROANOKE ISLAND, and Station Valdez into a single command. In addition, a Sector Field Office has been created to provide remote logistics support at Valdez, Alaska named Sector Field Office Valdez, which will be subordinate to Sector Anchorage. The Coast Guard has established a continuity of operations whereby all previous practices and procedures will remain in effect until superseded by an authorized Coast Guard official or document.

DATES: This notice is effective August 3, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD17 and are available for inspection or copying at Commander (dr), Seventeenth Coast Guard District, 709 West 9th Street, Room 771, Juneau, Alaska, 99802 between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Carl Hinshaw, Assistant Branch Chief for Enforcement, Seventeenth District Response Division at 907–463–2284.

SUPPLEMENTARY INFORMATION:

Discussion of Notice

Sector Anchorage is located at 510 L Street, Suite 100, Anchorage, Alaska 99501–1946. A Sector Field Office (SFO) will be created to provide remote logistics support at Valdez, AK named SFO Valdez. MSO Anchorage OPFAC 17–33280 will be cancelled. A Command Center supporting Sector Anchorage will be located at Anchorage, AK.

Sector Anchorage will be composed of a Response Department, Prevention Department and a Logistics Department. The Sector Command Center, Intelligence staff and Contingency Planning and Force Readiness staff will report directly to the Sector Commander and serve the Response, Prevention, and Logistics components. The Western Alaska Marine Inspection Zone and Captain of the Port Office are located in Anchorage, Alaska. MSO Valdez will be renamed Marine Safety Unit (MSU) Valdez and retain the authorities of Captain of the Port (COTP), Officer in Charge Marine Inspection (OCMI), Federal on Scene Coordinator (FOSC), and Federal Maritime Security Coordinator (FMSC). MSU Valdez will report directly to the Sector Commander. Vessel Traffic Service (VTS) Prince William Sound, a subunit of MSU Valdez, will be renamed VTS Valdez. SFO Valdez will report directly to the Sector Logistics Department. All existing missions and functions performed by MSO Anchorage will be realigned under this new organizational structure. The new Sector's area of responsibility for search and rescue (SAR) will be maintained in accordance with the District SAR plan.

We projected that by 2007, all existing administrative and operational missions and functions performed by Marine Safety Office Anchorage and prior subordinate units will be performed by Sector Anchorage. Administrative missions and functions performed by USCGC LONG ISLAND, USCGC MUSTANG, USCGC ROANOKE ISLAND, and Station Valdez will be performed by Sector Anchorage. All operational missions and functions performed by USCGC LONG ISLAND, USCGC MUSTANG, USCGC ROANOKE ISLAND, and Station Valdez will be assumed by Sector Anchorage upon stand up of a single Command Center at Sector Anchorage.

Sector Anchorage is responsible for all Coast Guard missions in the following zone: The Western Alaska Marine Inspection Zone and COTP Zone comprise that portion of the State of Alaska and the adjacent waters to the outermost extent of the EEZ, except for