Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product EVOXAC (Cevimeline HCl). EVOXAC is indicated for the treatment of symptoms of dry mouth in patients with Sjogren's Syndrome. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for EVOXAC (U.S. Patent No. 4,855,290) from the State of Israel, Israel Institute for Biological Research, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 14, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of EVOXAC 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 EVOXAC is 1,733 days. Of this time, 1,230 days occurred during the testing phase of the regulatory review period, while 503 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* April 16, 1995. The applicant claims March 17, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 16, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* August 27, 1998. The applicant claims August 26, 1998, as the date the new drug application (NDA) for EVOXAC (NDA 20–989) was initially submitted. However, FDA records indicate that NDA 20–989 was submitted on August 27, 1998.

3. *The date the application was approved:* January 11, 2000. FDA has verified the applicant's claim that NDA 20–989 was approved on January 11, 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 1,133 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments and ask for a redetermination by January 17, 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 May 19, 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 is 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 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–29188 Filed 11–15–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 18, 2002 (67 FR 64400). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portions of the meeting. The meeting was originally scheduled for November 18 and 19, 2002. However, due to administrative complications, the discussions on November 19, 2002, will be postponed until a later date. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2002 (67

FR 64400), FDA announced that a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee would be held on November 18 and 19, 2002. On page 64400, in the second column, the *Date and Time* and *Agenda* portions of the meeting are amended to read as follows:

Date and Time: The meeting will be held on November 18, 2002, from 8 a.m. to 5 p.m.

Agenda: On November 18, 2002, the committee will discuss the role of brain imaging as an outcome measure in phase 3 trials of putative therapeutic drugs for Alzheimer's disease; the discussions will not focus on specific drugs or on specific applications to the agency. The agency is considering whether brain imaging modalities can be utilized as surrogate markers; that is, as primary outcomes in definitive clinical trials to measure drug effect in lieu of clinical outcomes. The committee will specifically discuss the following issues in reference to each imaging modality:

1. How is the surrogate imaging modality best validated?

2. If one uses an imaging modality to support a disease-modifying effect claim, how does one establish that such an effect occurs?

3. Has any surrogate imaging modality been validated at the present time?

4. Even if no surrogate imaging modality has currently been validated, is it appropriate to use one or more such modalities as primary or ancillary outcome measures of efficacy in phase 3 clinical trials?

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

Dated: November 13, 2002.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–29294 Filed 11–14–02; 1:54 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2002

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2002, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
BARNABAS, RAVI ..... EGLIN AFB, FL	11/20/2002
BERSHATSKI, FANYA ..... STUDIO CITY, CA	11/20/2002
BOYKIN, LATRICE ..... LITTLE ROCK, AR	11/20/2002
BURNETTE, MARILYN ..... RICHTON, MS	11/20/2002
CARVAJAL, JOSE MIGUEL ..... COLEMAN, FL	11/20/2002
CHYORNY, ANNE ..... BEVERLY HILLS, CA	11/20/2002
CORDOVA, SANDRA ..... CHIMAYO, NM	11/20/2002
CRAIG, CHERYL ..... CALEDONIA, MS	11/20/2002
CRUMPTON, TERLESA M ..... MARIANNA, FL	11/20/2002
DARUKA, PATRICIA A ..... WARWICK, RI	11/20/2002
DAVIS, TRACEY DESHON ..... LITTLE ROCK, AR	11/20/2002
DAVIS, LINDA ..... LITTLE ROCK, AR	11/20/2002
DAVIS, ERNESIA LASHAWN .. N LITTLE ROCK, AR	11/20/2002
DECAPOTE, ONELIA ..... MIAMI, FL	11/20/2002
DUCKETT, BRUCE DEVLON .. FLINT, MI	11/20/2002
FERGUSON, PATRICIA M ..... VANCLEAVE, MS	11/20/2002
FISHER, SHERRY LYNNE ..... SPOKANE, WA	11/20/2002
GARCIA, MARTIZA ..... MIAMI, FL	11/20/2002
GARCIA, MARITZA ..... MIAMI, FL	11/20/2002
GINN, AARON C ..... ASHLAND, KY	11/20/2002
HARDY, ANDREW JR ..... OAK PARK, MI	11/20/2002
HIPPOLYTE, JOSEPH WABUZOH JR ..... LOMPOC, CA	11/20/2002
JRAGATSBANYAN, ART ..... LOS ANGELES, CA	11/20/2002
LANGINIKORO, HAROLD J ..... LYNNWOOD, WA	11/20/2002
NELMS, ANGELA ..... DAYTON, OH	11/20/2002
OSMAN, MOHAMED AWAD .... RICHMOND, VA	11/20/2002
PATTON, PATRICIA ANN ..... MARIANNA, AR	11/20/2002
PEREZ, JESUS ..... MIAMI, FL	11/20/2002
PRESTON, KENDA L ..... CANTON, OH	11/20/2002
RESPIRATORY DRUGGIST, INC ..... FOLEY, AL	11/20/2002
REYES, RAMON ..... HIALEAH, FL	11/20/2002
ROSS, SHAMEKEA ..... COLUMBUS, OH	11/20/2002
SCHMIDT, KATHLEEN LYNN ALEXANDRIA, MN	11/20/2002
SOILEAU, JOSEPH L ..... CAMERON, LA	11/20/2002
STEINBERG, EDWARD M ..... N MIAMI BEACH, FL	11/20/2002
SWIATEK, DAWN M ..... CHICAGO, IL	11/20/2002
TAGUMASI, ABNER ..... CARSON, CA	11/20/2002
VAUGHN, TRACY ALLEN ..... FOLEY, MN	11/20/2002
WALTZ, DAVID MATHEW ..... BEAVERTON, MI	11/20/2002
WATTS, VICKIE LANELL ..... TEMPLE, TX	11/20/2002
FELONY CONVICTION FOR HEALTH CARE FRAUD	
SODERSTROM, RITA MARLENE ..... CLIFTON, CO	11/20/2002
STROM, JOHN DAVID ..... STOW, OH	11/20/2002
FELONY CONTROL SUBSTANCE CONVICTION	
BAYBO, KAREN A ..... ST LOUIS, MO	11/20/2002
BURNS, JOANNE KLINA ..... PROSPECT PARK, PA	11/20/2002
DE LA FLOR, RICHARD ..... TOLEDO, OH	11/20/2002
HEMMERLING, BONNIE DEE FRANKFORT, IN	11/20/2002
KENTER, BARBARA SUSAN .. OMAHA, NE	11/20/2002
MAGGARD-ISON, EDNA LOUISE ..... KING CITY, MO	11/20/2002
PETRY, SAMANTHA L ..... ALDERSON, WV	11/20/2002
ROSENAUER, JENNIFER A .... CHESTERFIELD, MO	11/20/2002
SANTISTEVAN, KELLY K ..... HELPER, UT	11/20/2002
SMITH, PAMELA M ..... SINKING SPRING, PA	11/20/2002
PATIENT ABUSE/NEGLECT CONVICTIONS	
EDWARDS, JACQUELINE RENEE	11/20/2002