

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
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PROGRAM-RELATED CONVICTIONS

BARNABAS, RAVI	11/20/2002
EGLIN AFB, FL	
BERSHATSKI, FANYA	11/20/2002
STUDIO CITY, CA	
BOYKIN, LATRICE	11/20/2002
LITTLE ROCK, AR	
BURNETTE, MARILYN	11/20/2002
RICHTON, MS	
CARVAJAL, JOSE MIGUEL	11/20/2002
COLEMAN, FL	
CHYORNY, ANNE	11/20/2002
BEVERLY HILLS, CA	
CORDOVA, SANDRA	11/20/2002
CHIMAYO, NM	
CRAIG, CHERYL	11/20/2002
CALEDONIA, MS	
CRUMPTON, TERLESA M	11/20/2002
MARIANNA, FL	
DARUKA, PATRICIA A	11/20/2002
WARWICK, RI	
DAVIS, TRACEY DESHON	11/20/2002
LITTLE ROCK, AR	
DAVIS, LINDA	11/20/2002
LITTLE ROCK, AR	
DAVIS, ERNESIA LASHAWN ..	11/20/2002
N LITTLE ROCK, AR	
DECAPOTE, ONELIA	11/20/2002
MIAMI, FL	
DUCKETT, BRUCE DEVLON ..	11/20/2002
FLINT, MI	
FERGUSON, PATRICIA M	11/20/2002
VANCLEAVE, MS	
FISHER, SHERRY LYNNE	11/20/2002
SPOKANE, WA	
GARCIA, MARTIZA	11/20/2002
MIAMI, FL	
GARCIA, MARITZA	11/20/2002
MIAMI, FL	
GINN, AARON C	11/20/2002
ASHLAND, KY	
HARDY, ANDREW JR	11/20/2002
OAK PARK, MI	
HIPPOLYTE, JOSEPH	
WABUZOH JR	11/20/2002
LOMPOC, CA	
JRAGATSBANYAN, ART	11/20/2002
LOS ANGELES, CA	
LANGINIKORO, HAROLD J	11/20/2002

Subject city, state	Effective date
LYNNWOOD, WA	
NELMS, ANGELA	11/20/2002
DAYTON, OH	
OSMAN, MOHAMED AWAD	11/20/2002
RICHMOND, VA	
PATTON, PATRICIA ANN	11/20/2002
MARIANNA, AR	
PEREZ, JESUS	11/20/2002
MIAMI, FL	
PRESTON, KENDA L	11/20/2002
CANTON, OH	
RESPIRATORY DRUGGIST, INC	11/20/2002
FOLEY, AL	
REYES, RAMON	11/20/2002
HIALEAH, FL	
ROSS, SHAMEKEA	11/20/2002
COLUMBUS, OH	
SCHMIDT, KATHLEEN LYNN	
ALEXANDRIA, MN	
SOILEAU, JOSEPH L	11/20/2002
CAMERON, LA	
STEINBERG, EDWARD M	11/20/2002
N MIAMI BEACH, FL	
SWIATEK, DAWN M	11/20/2002
CHICAGO, IL	
TAGUMASI, ABNER	11/20/2002
CARSON, CA	
VAUGHN, TRACY ALLEN	11/20/2002
FOLEY, MN	
WALTZ, DAVID MATHEW	11/20/2002
BEAVERTON, MI	
WATTS, VICKIE LANELL	11/20/2002
TEMPLE, TX	

FELONY CONVICTION FOR HEALTH CARE FRAUD

SODERSTROM, RITA MARLENE	11/20/2002
CLIFTON, CO	
STROM, JOHN DAVID	11/20/2002
STOW, OH	

FELONY CONTROL SUBSTANCE CONVICTION

BAYBO, KAREN A	11/20/2002
ST LOUIS, MO	
BURNS, JOANNE KLINA	11/20/2002
PROSPECT PARK, PA	
DE LA FLOR, RICHARD	11/20/2002
TOLEDO, OH	
HEMMERLING, BONNIE DEE	
FRANKFORT, IN	
KENTER, BARBARA SUSAN ..	11/20/2002
OMAHA, NE	
MAGGARD-ISON, EDNA LOUISE	11/20/2002
KING CITY, MO	
PETRY, SAMANTHA L	11/20/2002
ALDERSON, WV	
ROSENAUER, JENNIFER A	11/20/2002
CHESTERFIELD, MO	
SANTISTEVAN, KELLY K	11/20/2002
HELPER, UT	
SMITH, PAMELA M	11/20/2002
SINKING SPRING, PA	

PATIENT ABUSE/NEGLECT CONVICTIONS

EDWARDS, JACQUELINE	
RENEE	11/20/2002