DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–E–0166]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SOLIRIS 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written or electronic comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 Director 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 biologic product, SOLIRIS (eculizumab). SOLIRIS is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SOLIRIS (U.S. Patent No. 6,355,245) from Alexion Pharmaceuticals, 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 May 6, 2008, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of SOLIRIS 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 SOLIRIS is 1,360 days. Of this time, 1,177 days occurred during the testing phase of the regulatory review period, while 183 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 (the act) (21 U.S.C. 355(i)) became effective*: June 27, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 27, 2003.

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)*: September 15, 2006. FDA has verified the applicant's claim that the biologics license application (BLA) for SOLIRIS (BLA 125166/0) was initially submitted on September 15, 2006.

3. *The date the application was approved*: March 16, 2007. FDA has verified the applicant's claim that BLA 125166/0 was approved on March 16, 2007.

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 735 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 May 4, 2009. 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 August 31, 2009. 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: February 17, 2009.

Jane A. Axelrad,

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

[FR Doc. E9–4526 Filed 3–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Psychopharmacologic Drugs 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: Psychopharmacologic Drugs 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 April 7 and 8, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd, Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Yvette Waples, 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, fax: 301–827–6776, e-mail: yvette.waples@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 7, 2009, the committee will discuss safety and efficacy issues of new drug application (NDA) 20–644, sertindole (Serdolect) tablets, Lundbeck USA, proposed for the treatment of schizophrenia. On April 8, 2009, the committee will discuss safety and efficacy issues of supplemental new drug applications (sNDAs) 22–047/S–010/S–011/S–012, quetiapine b6 maleate (Seroquel XR), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of major depressive disorder and 22–047/S–014/S–015, Seroquel XR (quetiapine maleate), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of generalized anxiety disorder. Particular safety issues for discussion on April 8, 2009, regarding the Seroquel XR applications are concerns regarding exposing a greatly expanded population to a drug with known metabolic side effects and a possible risk of tardive dyskinesia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

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 March 27, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. 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 March 18, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 23, 2009.

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 John Lauttman at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: February 26, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–4523 Filed 3–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for comments on proposed change to the Reimbursement of Travel and Subsistence Expenses Program Eligibility criteria.

SUMMARY: HRSA published the final eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses Program in the **Federal Register** on October 5, 2007 (72 FR 57049). A subsequent amendment to the Program guidelines was published in the **Federal Register** on June 20, 2008 (73 FR 35143). HRSA is requesting public comments concerning recommended changes to a specific section of the reimbursement program eligibility guidelines. On page 35145, under the *Qualifying Expenses* Section, the first paragraph states:

For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, *qualifying expenses* presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:

(1) Donor evaluation, clinic visit or hospitalization,

(2) Hospitalization for the living donor surgical procedure, and/or

(3) Medical or surgical follow-up clinic visit or hospitalization within 90 days following the living donation procedure.

HRSA wishes to amend the first item of this paragraph to read: ''(1) Donor evaluation (including, if applicable, clinic visits or hospitalization) and/or''. This is a technical change to clarify that the expenses referred to are all related to the donor evaluation. In addition, HRSA wishes to amend the third item of this paragraph to read: ''(3) Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist).'' This change in the follow-up period would bring the National Living Donor Assistance Center follow-up period in line with the Organ Procurement and Transplantation Network policy requiring follow-up of living organ donors for a period of 2 years. Adding the exceptional circumstances language at the end of this item would allow reimbursement for post-surgical follow-