August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SPIRIVA HANDIHALER represented the first permitted commercial marketing or use of the product. 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 SPIRIVA HANDIHALER is 3,318 days. Of this time, 2,557 days occurred during the testing phase of the regulatory review period, while 761 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*: January 1, 1995. The applicant claims February 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 1, 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*: December 31, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Spiriva HandiHaler (NDA 21–395) was initially submitted on December 31, 2001.

3. *The date the application was approved*: January 30, 2004. FDA has verified the applicant's claim that NDA 21–395 was approved on January 30, 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 1,421 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 28, 2006, submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 26, 2006, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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: January 5, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1050 Filed 1–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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 meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of January 6, 2006 (71 FR 943). The amendment is being made to reflect a change in the *Date and Time* portion of the document. The date of this meeting is being changed. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512542. Please call the information line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 6, 2006, FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on March 15, 2006, from 8 a.m. to 5 p.m. On page 943, in the 2d column, the *Date and Time* portion of the document is amended to read as follows:

Date and Time: The meeting will be held on March 13, 2006, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 17, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1003 Filed 1–26–06; 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; 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: Peripheral and Central Nervous System 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 March 7, 2006, from 8 a.m. to 5 p.m.

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

Contact Person: Sohail Mosaddegh, 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: *mosaddeghs@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss TYSABRI (natalizumab) biologic license application 125104/15; Biogen Idec Inc., for an indication in patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. The committee will discuss the risks (including progressive multifocal leukoencephalopathy) associated with TYSABRI (natalizumab) administration, its efficacy in the treatment of multiple sclerosis relapses