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

and/or disability, its possible return to the marketplace, and its proposed risk management plan(s).

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)'' (click on the year 2006 and scroll down to PCNS meetings.)

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 by February 28, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2006, 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.

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 Sohail Mosaddegh 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: January 17, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1006 Filed 1–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Request for Generic Clearance To Conduct Voluntary Customer/Partner Surveys

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Voluntary Customer Satisfaction Surveys.

Type of Information Collection Request: Extension. OMB Control No. 0925–0476, with an expiration date of May 31, 2006.

Need and Use of Information Collection: Executive Order 12962 directed agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. Additionally, since 1994, the NLM has been a ''Federal Reinvention Laboratory'' with a goal of improving its methods of delivering information to the public. An essential strategy in accomplishing reinvention goals is the ability to periodically receive input and feedback from customers about the design and quality of the services they receive.

The NLM provides significant services directly to the public including health providers, researchers, universities, other federal agencies, state and local governments, and to others through a range of mechanisms, including publications, technical assistance, and Web sites. These services are primarily focused on health and medical information dissemination activities. The purpose of this submission is to obtain OMB's generic approval to continue to conduct satisfaction surveys of NLM's customers. The NLM will use the information provided by individuals and institutions to identify strengths and weaknesses in current services and to make improvements where feasible. The ability to periodically surveys NLM's customers is essential to continually update and upgrade methods of providing high quality service.

Frequency of Response: Annually or biennially.

Affected Public: Individuals or households; businesses or other for profit; State or local governments; Federal agencies; non-profit institutions; small businesses or organizations.

Type of Respondents: Organizations, medical researchers, physicians and other health care providers, librarians, students, and the general public. Annual reporting burden is as follows:

Title of survey	Type of survey	Number of respondents	Estimated response time	Burden hours
ClinicalTrials.gov and Protocol Registration System	Web-based	2000	.167	334
Consumer Information Health Seeking Process	Web-based	500	.5	250
Consumer Knowledge of Health-Related Concepts	Interviews/Questionnaires (in person)	200	.5	100
Comprehension of Consumer Health Materials Online	Interviews/Scenarios (in person)	40	1	40
Patient Information Seeking and Symptom Management Decision Making	Interview/Observation (in person)	150 (15 × 10 sessions)	.5	75
	18 (3 × 6 sessions)	.....	.5	9
		.....	.....	84
Evaluation of Genetics Home Reference Survey	Web-based	950 (200 + 500 + 250)	.5 .4175 .4175	100 209 104
		.....	.....	413
PubMed	Web-based	2,000	.0835	167
Entrez	Web-based	1,500	.0835	128