

address at <http://www.cms.hhs.gov/PaperworkReductionActof1995/> or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed to the designees referenced below by *April 14, 2006*:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Bonnie L Harkless,

and,

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 23, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 06-1921 Filed 3-2-06; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0427]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by April 3, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

Filing Objections and Requests for a Hearing on a Regulation or Order—(OMB Control Number 0910-0184)—Extension

Under part 12 (21 CFR part 12), § 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)), sets forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection for which a hearing has been requested must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of November 16, 2005 (70 FR 69577), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	10	1	10	20	200

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-3020 Filed 3-2-06; 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 May 17, 2006, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301-977-8900.

Contact Person: Darrell Lyons, 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, e-mail: Darrell.Lyons@fda.hhs.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 supplemental new drug application (NDA) 20823, SE1-016, EXELON (rivastigmine tartrate) Capsules (1.5 milligrams (mg), 3.0 mg, 4.5 mg, and 6.0 mg), Novartis Pharmaceuticals Corp., for the proposed indication of the treatment of mild to moderate dementia associated with Parkinson's disease. 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." (Click on the year 2006 and scroll down to the previously named committee).

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 May 3, 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 May 3, 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 Darrell Lyons 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: February 24, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6-3021 Filed 3-2-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by sponsors of approved drug and biological products. This is the agency's report on the status of the studies sponsors have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6466, Silver Spring, MD 20993-0002, 301-796-0700; or Robert Yetter, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1400 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the Modernization Act (Public Law 105-115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies (section 506B of the act (21 U.S.C. 356b)) for human drug and biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually

providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment.

On December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The final rule, published on October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 30, 2001. The regulations apply only to human drug and biological products. They do not apply to animal drug or to biological products that also meet the definition of a medical device.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70, and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated, and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is