

Dated: October 25, 2005.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

2005 White House Conference on Aging

AGENCY: Administration on Aging, HHS.

ACTION: Notice of conference call.

SUMMARY: Pursuant to section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2), notice is hereby given that the Policy Committee of the 2005 White House Conference on Aging will vote on the Annotated Agenda for the WHCoA and may discuss other items related to finalizing the 2005 WHCoA during a conference call. The conference call will be open to the public to listen, with call-ins limited to the number of telephone lines available. Individuals who plan to call in and need special assistance, such as TTY, should inform the contact person listed below in advance of the conference call. This Notice is being published less than 15 days prior to the conference call due to scheduling problems.

DATES: The conference call will be held on Thursday, November 3, 2005, at 5 p.m., eastern standard time.

ADDRESSES: The conference call may be accessed by dialing, U.S. toll-free, 1-800-857-0419, passcode: 6045175, on the date and time indicated above.

FOR FURTHER INFORMATION CONTACT: Kim Butcher, (301) 443-2887, or e-mail at Kim.Butcher@whcoa.gov. Registration is not required. Call in is on a first come, first-served basis.

SUPPLEMENTARY INFORMATION: Pursuant to the Older Americans Act Amendments of 2000 (Pub. L. 106-501, November 2000), the Policy Committee will hold a meeting by conference call to vote on the Annotated Agenda for the 2005 White House Conference on Aging. The public is invited to listen by dialing the telephone number and using the passcode listed above under the Address section.

Dated: October 28, 2005.

Edwin L. Walker,

Deputy Assistant Secretary for Policy and Programs.

[FR Doc. 05-21823 Filed 11-1-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0502]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Study to Measure the Compliance of Prescribers With the Contraindication of the Use of Triptans in Migraine Headache Patients With Vascular Disease

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 December 2, 2005.

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:

Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Study to Measure the Compliance of Prescribers With the Contraindication of the Use of Triptans in Migraine Headache Patients With Vascular Disease

Migraine headache affects about 20 million Americans. Over the last decade, numerous drugs in a category referred to as "triptans" have been shown to be efficacious in treating migraine headache and have been approved for this condition. Triptan drugs have been prescribed to millions of patients. However, triptans are routinely contraindicated in patients with vascular diseases due to associated rare occurrence of myocardial

infarction, stroke, and other ischemic events. In view of the wide use of this class of drugs and the potential impact on public health as a result of this contraindication, FDA believes it would be significantly helpful to better understand the prescribing practices for these drugs.

FDA plans to examine the feasibility of using the Internet to recruit triptan-user migraine headache patients to determine whether prescribers follow the labeling recommendation by not prescribing this class of drugs to patients with pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes or with cardiac risk factors.

FDA intends to solicit patients over the Internet to identify a group of triptan users. FDA will then ask these patients to complete a questionnaire about their medical history with a focus on vascular diseases. Following that, FDA will request medical records from a sample of the patients and review the submitted records to verify the medical history and the presence, if any, of cardiovascular, cerebrovascular, or peripheral vascular ischemic diseases. FDA will also collect information about patients' demographics, route of administration (oral, injection, intranasal), and duration of exposure to triptans.

In the **Federal Register** of November 17, 2003 (68 FR 64902), FDA published a notice requesting comment on this information collection. Three comments were received in response to the notice, each raising several issues, as follows:

(1) One comment contended that the agency has not put forth an adequate foundation for conducting the study. The comment said that no data or other information has been described to justify the expenditure of government resources and the imposition of information collection burdens on the industry. The comment said that the only rationale consists of speculation that "it would be of great use to better understand the prescribing practices as a result of this contraindication [use of triptans in patients with vascular diseases]." The comment contended that this is an insufficient predicate for conducting publicly-funded research that casts a cloud of suspicion over a class of currently marketed drug products that provide great clinical benefit to patients who suffer from migraine headaches. The comment said that the **Federal Register** notice provides no information about FDA's view of the relative role of data derived from the survey in relation to data from controlled clinical studies, epidemiology studies, and spontaneous medical event reports.