Dated: November 10, 2003.

James D. Seligman,

Chief Information Officer, Office of the Chief Operations Officer, Centers for Disease Control and Prevention.

[FR Doc. 03–28605 Filed 11–14–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–4 p.m., December 9, 2003, 8 a.m.–5 p.m., December 10, 2003.

Place: The Westin Casuarina, 160 East Flamingo Road, Las Vegas, Nevada 89109, telephone 702/836–9775, fax 702/836–9776.

Status: Open 8 a.m.–4 p.m., December 9, 2003. Open 8 a.m.–12:30 p.m., December 10, 2003. Closed 2 p.m.–5 p.m., December 10, 2003.

Background: The Advisory Board on Radiation and Worker Health (''the Board'') was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, through the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by the National Institute for Occupational Safety and Health (NIOSH) for qualified cancer claimants, and advice on the addition of classes of workers to the Special Exposure Cohort.

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was renewed on August 3, 2003 and the President has completed the appointment of members to the Board to ensure a balanced representation on the Board.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: The meeting will convene in open session from 8 a.m.–4 p.m. on December 9, 2003 and 8 a.m.–12:30 p.m. on December 10, 2003, to address matters related to NIOSH and Department of Labor updates, an Integrated Module Bioassay Analysis (IMBA) Update, site profile status and roll-out, a Sanford Cohen and Associates brief, reports from the Workgroup on Options for Evaluating Interviews and the Research Issues Workgroup, as well as Board discussion. The remainder of the meeting will proceed in closed session.

The purpose of the closed sessions is to include development, review, and discussion of a proposed Independent Government Cost Estimate (IGCE) for a technical support contract intended to assist the Board in fulfilling its statutory duty to advise the Secretary, HHS regarding dose reconstruction efforts under the EEOICPA. The IGCE will include contract cost estimates, the disclosure of which would adversely impact the Government's negotiating position and strategy in regards to this contract by giving potential bidders an undue advantage in determining the price associated with their bids. The information being discussed will include information of a confidential nature.

This portion of the meeting will be closed to the public in accordance with provisions set forth regarding subject matter considered confidential under the terms of 5 U.S.C. 552b(c)(9)(B), 48 CFR 5.401(b)(1) and (4), and 48 CFR 7.304(d), and the Determination of the Director of the Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Pub. L. 92–463.

A summary of this meeting will be prepared and submitted with 14 days of the close of the meeting.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 10, 2003.

Betsey Dunaway,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–28600 Filed 11–14–03; 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; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's burden estimates to distribute an Internet-based questionnaire to measure the compliance of prescribers with the contraindication of the use of triptans in migraine headache patients with vascular disease.

DATES: Submit written or electronic comments on the collection of information by January 16, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Migraine headaches affect about 20 million Americans. Over the last decade, a category of drugs referred to as triptans, has been shown to be efficacious in treating migraine and has been prescribed to millions. 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, it would be of great use to better understand the prescribing practices as a result of this contraindication.

FDA plans to use the Internet to recruit triptan-user migraine headache patients to determine whether prescribers follow the labeling recommendation to avoid prescribing this class of drugs to patients with pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes or with cardiac risk factors. The study is intended to measure the proportion of patients that were prescribed triptans although they have pre-existing cardiovascular, cerebrovascular, or peripheral vascular syndromes.

Soliciting patients over the Internet will identify a cohort of triptan users. These patients will then be asked to fill out a questionnaire about their medical history with a focus on vascular diseases. Following that, a sample of patients' medical records will be solicited and reviewed to verify the medical history. Prevalence of cardiovascular, cerebrovascular, or peripheral vascular ischemic diseases among migraine patients using triptans will be estimated. Information about patients' demographics, route of administration (oral, injection, intranasal), and duration of exposure to triptans will also be collected.

There are no available estimates about the rates of various vascular diseases and cardiac risk factors among migraine headache patients using triptans. The current study is considered a pilot study aimed at providing estimates of such rates to be used as a basis for future studies. Although FDA recognizes that the study population obtained through Internet-based recruitment may not reflect the population of triptan users at large, a signal of substantial prescribing to patients with vascular contraindications in this selected population may warrant further action on the sponsor's part to improve risk management. Improvement of risk management may include further study of the problem, a labeling change, educational programs performed by the sponsor, or increased restrictions on prescribing.

FDA estimates that approximately 500 persons will voluntarily complete the questionnaire. The estimated time for completing each questionnaire is approximately 2 hours, resulting in a total burden of 1,000 hours per year. The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
500	1	500	2	1,000

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

Dated: November 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28581 Filed 11–14–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage