

Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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.

**Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (OMB Control Number 0910-0374)—Extension**

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the Food and Drug Administration Modernization Act

of 1997 (FDAMA), provides that a food producer may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences. Under these sections of the act, a food producer that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), FDA announced the availability of a guidance entitled "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body." The guidance provides the agency's interpretation of terms central to the submission of a notification and the agency's views on the information that should be included in the

notification. The agency believes that the guidance will enable food producers to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the act. In addition to the information specifically required by the act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. FDA intends to review the notifications it receives to ensure that they comply with the criteria established for them by the act.

In the **Federal Register** of March 26, 2002 (67 FR 13786), the agency requested comments on the proposed information collection. One comment was received that did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Basis of Burden	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 403(r)(2)(G) nutrient content claims	.....	1	250	250	.....
Section 403(r)(3)(c)	2	1	2	450	900
Guidance for notifications	3	1	3	1	3
Totals					1,153

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

These estimates are based on FDA's experience with health claims and nutrient content claims and with other similar notification procedures that fall under its jurisdiction. Because the claims are based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences or one of its subdivisions, FDA believes that the information submitted with a notification will either be provided as part of the authoritative statement or readily available as part of the scientific literature to firms wishing to make claims. Presentation of a supporting bibliography and a brief balanced account or analysis of this literature should be fairly straightforward.

Dated: June 21, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-16343 Filed 6-27-02; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Cardiovascular and Renal 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:* Cardiovascular and Renal 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 July 18, 2002, from 8 a.m. to 5 p.m. and on July 19, 2002, from 8 a.m. to 3 p.m.

*Location:* Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD, 301-652-2000.

*Contact Person:* Jayne E. Peterson, 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, petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On July 18, 2002, beginning at 8 a.m., the committee will discuss supplemental new drug application (SNDA) 20-838/S-015, ATACAND (candesartan cilexetil) Tablets, AstraZeneca LP, for a proposed claim of comparative efficacy of candesartan cilexetil and losartan in hypertension. Beginning at 1 p.m., the committee will discuss new drug application (NDA) 21-387, PRAVIGARD PAC (pravastatin sodium/aspirin co-packaged product), Bristol-Myers Squibb Co., proposed for long-term management to reduce the risk of cardiovascular events (death, nonfatal myocardial infarction, myocardial revascularization procedures, and ischemic stroke) in patients with clinically evident coronary heart disease. On July 19, 2002, the committee will discuss NDA

21-188, VANLEV (omapatrilat) Bristol-Myers Squibb Co., proposed for the treatment of hypertension. The background material for this meeting will be posted 1 working day before the meeting on the FDA Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>.

**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 July 11, 2002. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. and 3:15 p.m. and 3:45 p.m. on July 18, 2002, and between approximately 10:15 a.m. and 10:45 a.m. on July 19, 2002.

Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 11, 2002, 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 Jayne E. Peterson 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: June 21, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 02-16351 Filed 6-27-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### National Mammography Quality Assurance 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:** National Mammography Quality Assurance 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 August 26, 2002, from 9 a.m. to 6 p.m.

**Location:** Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

**Contact Person:** Charles Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will receive information on the American College of Radiology Imaging Network trial of full field digital mammography (FFDM), potential new applications of FFDM such as tomosynthesis, facility inspection findings, and the status of current inspection followup actions, and changes to the Mammography Quality Standards Act (the MQSA) compliance guidance. The committee will also receive updates on the status of accreditation and certification of FFDM, States as certification agencies under the MQSA, reauthorization of the MQSA, and the inspection demonstration project. The MQSA compliance guidance documents, which are in a question-and-answer format, are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography/guidance-docs.html>. This guidance is being updated continually in response to questions that FDA receives from the public.

**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 August 16, 2002. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 16, 2002, 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.

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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 Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, 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: June 21, 2002.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 02-16352 Filed 6-27-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4736-N-06]

### Notice of Proposed Information Collection for Public Comment for Correcting and Challenging Date for the Indian Housing Block Grant Formula Allocation

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The department is soliciting public comments on the subject proposal.

**DATES:** *Comment Due Date:* August 27, 2002.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, The Department of Housing & Urban Development, 451-7th Street, SW., Room 8226, Washington, DC 20410-6000.

**FOR FURTHER INFORMATION CONTACT:** Mildred M. Hamman, (202) 708-3642,