7. Office of Operations Management (FAY)

- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/Chief Operating Officer (COO) and the Agency.
- Prepares and presents recommendations to the Administrator, Deputy Administrator/ COO, other high level CMS, and Department officials on planning, leadership, implementation, and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.
- With appropriate CMS components to collect and disseminate data on health care and insurance market trends that affect CMS's business risk profile. The Risk Management Staff has the lead for monitoring indicators of risk associated with the operations of CMS and our business partners.
- Surveys risk assessment techniques in use in the private and public sectors and identifies and applies the most useful ones for CMS. Helps develop new risk assessment techniques and keeps abreast of methodological developments in the professional literature.
- Promotes and teaches risk assessment methods to business owners throughout CMS. Promotes awareness of the importance of risk analysis as a component of business planning and trains CMS staff in specific techniques and their applicability in particular situations.
- Educates and reaches out to the public and internal CMS staff on the Health Insurance Portability and Accountability Act (HIPAA) issues. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquires on HIPAA issues, and liaisons with industry representatives.
- Provides technical coordination regarding development of HIPAA tools, including transaction testing, and coordinates requirements for Enumeration systems.
- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.
- Participates in Agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.

Specific Project Management Functions

- Develops, in conjunction with staff in CMS centers and offices, major project plans, implementation schedules and post implementation evaluations.
- Promotes project planning principles throughout the Agency and provides technical guidance to the Agency on project planning and management techniques.
- Reports to the Deputy Administrator/COO and senior officials on progress of Agency priority projects. Negotiates with and supports project and component heads regarding project schedules, progress, etc.
- Prepares and presents recommendations to senior officials regarding major projects.
- Analyzes and evaluates project time lines, schedules, and new methodologies. Evaluates and recommends project management alternatives to the Deputy Administrator/COO and the Agency.
- Conducts process control analysis and tracking to ensure projects are running smoothly.
- Prepares and presents recommendations to the Administrator, Deputy Administrator/COO, and other high level CMS and Department officials on planning, leadership, implementation and policy issues concerning modifications to existing and proposed operating policies that will improve the administration and operations of programs and the Agency as a whole.

Specific Operational Review Functions

- Plans and conducts targeted operational reviews and recommends process and policy improvements to improve the operations of the Agency. The subjects of these reviews will be determined through regular periodic consultation with the Project Management Staff, Risk Management Staff, the Director of the Office of Operations Management, and the Deputy Administrator/COO. Drafts written reports summarizing conclusions and presents findings to appropriate officials for follow-up actions.
- Reviews and evaluates enterprise-wide programs, projects, and processes to assess their effectiveness and efficiency, compliance with laws and regulations, or adequacy of management processes.
- Provides consulting services internally to Agency management and staff to identify processes or contracts that need improvement, to develop improvement strategies, and to monitor processes and improvements over time.
- Participates in agency-wide initiatives to streamline operations, improve accountability and performance, and implement management best practices. Provides leadership, training, and coaching in the implementation of the initiatives. Promotes a continuous improvement ethos.
- Collaborates with the Risk Management Staff, Project Management Staff, and CMS senior management to identify and address enterprise-wide risk factors that lead to ineffective or inefficient operations.
- Identifies operational vulnerabilities in CMS and develops and executes an operational review plan for each fiscal year, subject to approval by the Deputy Administrator/COO and other senior leadership of CMS.

Dated: June 5, 2002.

Ruben J. King-Shaw, Jr.,

Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 02–14949 Filed 6–27–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0102]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 29, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235,

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[1]

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

[1] 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