these opportunities and assisting them in identifying prescription discount card programs that are reputable and offer quality customer service, these beneficiaries can reduce their out-of-pocket expenditures for drugs substantially. Further, we believe under this initiative that beneficiaries will be more compliant with prescription drug treatment plans and consequently will make more optimal use of their Medicare-covered services. This initiative is consistent not only with the Secretary's duty under the Medicare program to educate beneficiaries, but is also consistent with the Secretary's duties under the Social Security Act to effectuate the purposes of the Medicare program.

This collection of information is structured on the requirements already articulated in the final rule entitled, ''Medicare-Endorsed Prescription Drug Card Assistance Initiative'', published on September 4, 2002 (67 FR 56618).

CMS is requesting OMB review and approval of this collection by January 7, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by December 13, 2002. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection.

Title of Information Collection: Medicare-Endorsed Prescription Drug Card Assistance Initiative.

Form No.: CMS–10076 (OMB# 0938–NEW).

Use: CMS is soliciting applications from prescription discount card programs so that it may endorse qualifying programs for Medicare beneficiaries. CMS, on its website, and the endorsed programs, on request, will make information available for Medicare beneficiaries to use to compare the programs for possible enrollment in one of them.

Frequency: Annually, bi-annually, monthly.

Affected Public: Business or other for-profit, Not-for-profit institutions.

Number of Respondents: 15.

Total Annual Responses: 15.

Total Annual Hours: 5,444.

Background

The Centers for Medicare and Medicaid Services (CMS) is seeking applications from qualified entities interested in entering into a Medicare endorsement agreement for their prescription discount card program. The general purpose of this Medicare endorsement agreement will be to publicize information that allows Medicare beneficiaries to compare prescription drug discount cards, assist Medicare beneficiaries in understanding and accessing private market methods for securing discounts on the purchase of prescription drugs, and raise beneficiary awareness of prescription drug discount card programs available in the commercial market. Approximately 9 million Medicare beneficiaries are without drug coverage at any point in a year. We expect this initiative will help beneficiaries, particularly those who lack prescription drug coverage, understand how drug discount card programs can lower beneficiary out-of-pocket prescription drug expenses. Further, we believe under this initiative that beneficiaries will be more compliant with prescription drug treatment plans and consequently will make more optimal use of their Medicare-covered services. This effort is not, in any way, an offer of a Medicare-reimbursed drug benefit.

Readers can find the application for this initiative on the Web site listed below. It is the final version subject to OMB approval.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.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 record keeping requirements must be mailed and/or faxed to the designees referenced below, by December 13, 2002:

OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503, Fax: 202–395–6974,

And,

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Julie Brown, Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, Fax: 410–786–3064.

Dated: November 20, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02–30367 Filed 11–27–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0280]

Agency Information Collection Activities; Submission for OMB 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 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 December 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: JonnaLynn P. Capezzuto, Office of Information Resources Management (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

The provision in 21 CFR 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) (21 CFR 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 21 CFR 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 July 8, 2002 (67 FR 45125), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

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

The burden estimate for this collection of information is based on past filings. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 10 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: November 21, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30157 Filed 11–27–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Radiological Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Radiological Devices Panel of the Medical Devices 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 December 10, 2002, from 8:30 a.m. to 5 p.m.

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

Contact Person: Robert J. Doyle, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12526. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a device that produces a computerized thermal image of the breast of women recommended for biopsy.

Background information, including the agenda and questions for the committee, will be available to the public one business day before the meeting, on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*. Material will be posted on December 9, 2002.

Procedure: On December 10, 2002, from 8:30 a.m. to 12:30 p.m., and from 1 p.m. to 5 p.m., the meeting is open to the public. 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 December 3, 2002. On December 10, 2002, oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m., and for an additional 30 minutes near the end of the committee deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 3, 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.

Closed Committee Deliberations: On December 10, 2002, from 12:30 p.m. to 1 p.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future agency issues.

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 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: November 21, 2002.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 02–30158 Filed 11–27–02; 8:45 am]

BILLING CODE 4160–01–S