(3) years, beginning on September 4, 2001:

(1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 (Debarment Regulations);

(2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 01–24157 Filed 9–26–01; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

In accordance with section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), the Agency for Healthcare Research and Quality (AHRQ) announces meetings of scientific peer review groups. The subcommittees listed below are part of the Agency's Health Services Research Initial Review Group Committee.

The subcommittee meetings will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications are to be reviewed and discussed at these meetings. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

1. *Name of Subcommittee:* Health Care Research Training.

Date: September 27–28, 2001 (Open from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: AHRQ, Executive Office Center, 6010 Executive Boulevard, 4th Floor Conference Center, Rockville, Maryland 20852.

2. *Name of Subcommittee:* Health Care Technology and Decision Sciences.

Date: October 4–5, 2001 (Open from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: AHRQ, Executive Office Center, 6010 Executive Boulevard, 4th Floor Conference Center, Rockville, Maryland 20852.

3. *Name of Subcommittee:* Health Systems Research.

Date: October 18–19, 2001 (Open from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: AHRQ, Executive Office Center, 6010 Executive Boulevard, 4th Floor Conference Center, Rockville, Maryland 20852.

4. *Name of Subcommittee:* Health Research Dissemination and Implementation.

Date: October 29–30, 2001 (Open from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: AHRQ, Executive Office Center, 6010 Executive Boulevard, 4th Floor Conference Center, Rockville, Maryland 20852.

5. *Name of Subcommittee:* Health Care Quality and Effectiveness Research.

Date: October 25–26, 2001 (Open from 8 a.m. to 8:15 a.m. and closed for remainder of the meeting).

Place: AHRQ, Executive Officer Center, 6010 Executive Boulevard, 4th Floor Conference Center, Rockville, Maryland 20852.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of the meetings should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594–1846.

This notice is being published less than 15 days prior to the September 27–28 and October 4–5 meetings due to the time constraints of reviews and funding cycles.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: September 20, 2001.

John M. Eisenberg, M.D.

Director.

[FR Doc. 01–24225 Filed 9–26–01; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–10045]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Survey: Texas; *Form No.:* CMS–10045 (OMB# 0938–NEW); *Use:* This survey is necessary to collect information on beneficiary access, quality of services, diversity of product selection, industry competitiveness, and financial performance from DMEPOS suppliers. These key elements of the evaluation of Medicare's competitive bidding demonstration cannot be thoroughly evaluated without a survey of suppliers. The information will be presented to CMS and to Congress, who will use the results to determine whether the demonstration should be extended to other sites. The respondents will be companies who supply DMEPOS to Medicare beneficiaries.; *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 384; *Total Annual Responses:* 384; *Total Annual Hours:* 768.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's WEB SITE ADDRESS at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 4, 2001.

John P. Burke III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–24153 Filed 9–26–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0398]

Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of OTC drug products.

DATES: Submit written or electronic comments on the collection of information by November 26, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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 L. Nelson, Office of Information Resources Management (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 including each proposed extension of an existing 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: (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.

Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products. The rule requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by the OMB because they are ''originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 of the labeling requirements (21 CFR 201.66) requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d). FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the labeling requirements. Therefore, the majority of respondents will be able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), the agency stated that of the 39,310 stock keeping units (SKUs) (individual products, packages, and sizes) currently marketed under a final monograph, approximately 32 percent, or 12,573 products, may necessitate labeling changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average of, 4 hours, for a total of 50,292 hours per year. The burden was expected to be a one-time burden.

The agency stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs currently marketed, or 26,737 products, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with this rule. FDA estimated that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. The burden was expected to be a one-time burden.

Finally, the agency estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments will be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) will be required for labeling changes under