

comparison to a legally marketed predicate.

This draft guidance represents the agency's current thinking on labeling of diagnostic performance for new laboratory tests. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the "Draft Guidance on Labeling for Laboratory Tests" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1352) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the "Draft Guidance on Labeling for Laboratory Tests," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at "http://www.fda.gov/cdrh".

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch

between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 24, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99-23229 Filed 9-7-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-285]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

ACTION: Comment request.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

Title of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Retirement Benefit Information;

Form No.: HCFA-R-285 (OMB# 0938-0769);

Use: This form will be used to obtain information regarding whether a beneficiary is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan subsidizes the beneficiary's Part A premium. The purpose in collecting this information is to determine and provide those eligible beneficiaries, with free Part A Medicare coverage;

Frequency: On Occasion;
Affected Public: State, Local or Tribal Government, and Individuals or Households;

Number of Respondents: 1,500;
Total Annual Responses: 1,500;
Total Annual Hours: 375.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 26, 1999.

John P. Burke III,

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

[FR Doc. 99-23312 Filed 9-7-99; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Health Professions and Nurse Education Special Emphasis Panel (SEP) Meetings.

Name: Residency Training in Primary Care Peer Review Group I.

Date and Time: December 6-9, 1999, 8:00 a.m. to 6:00 p.m.

Place: Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, Maryland 20910.

Open on: December 6, 1999, 8:00 a.m. to 10:00 a.m.

Closed on: December 6, 1999, 10:00 a.m. to 6:00 p.m.; December 7-9, 1999, 8:00 a.m. to 6:00 p.m.

Name: Residency Training in Primary Care Peer Review Group II.

Date and Time: December 13-16, 1999, 8:00 a.m. to 6:00 p.m.