bioavailability (BA) measures in investigational new drug applications, new drug applications, abbreviated new drug applications, and their amendments and supplements. This draft guidance is a modification of a preliminary draft guidance entitled ''In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches'' published in December 1997, and this draft guidance updates a July 1992 FDA guidance entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design''. When finalized, this draft guidance will replace both the 1992 and 1997 guidances.

DATES: Written comments may be submitted on the draft guidance document by November 8, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Average, Population, and Individual Approaches to Establishing Bioequivalence'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mei-Ling Chen, Center for Drug Evaluation and Research (HFD–870), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5919.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'' The draft guidance provides recommendations to sponsors and/or applicants intending to perform in vivo and in vitro BE studies based on comparisons of in vivo and in vitro BA measurements. In an earlier guidance entitled ''Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design,'' FDA recommended that an average BE approach be used to establish BE between test and reference drug products. Because of the limitations in the average BE approach, and after extensive intramural and extramural discussions, the Center for Drug Evaluation and Research (CDER) now recommends that the average BE approach be supplemented by two new approaches, population and individual BE. This draft guidance focuses on how to use each approach once a specific criterion has been chosen.

This draft guidance is one of a set of seven core guidances being developed to provide recommendations on how to meet provisions of part 320 (21 CFR part 320) for orally administered drug products and drug products for local action. Taken together, the seven guidances are designed to clarify the studies needed to document product quality BA/BE for all drug products regulated by CDER in accordance with the provisions in part 320. A further intent is to reduce regulatory burden where feasible.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 2, 1997). It represents the agency's current thinking on average, population, and individual approaches to establishing BE. 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 an approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to 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 26, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23228 Filed 9–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2726]

Medical Devices; Draft Guidance on Labeling for Laboratory Tests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled '' Draft Guidance on Labeling for Laboratory Tests.'' This draft guidance is not final nor is it in effect at this time. The draft guidance is intended to identify the information that should be provided to FDA for labeling the diagnostic performance of laboratory tests. FDA intends to recognize two major categories of endpoints for assessing diagnostic performance of new ''in vitro diagnostic'' assays.

DATES: Written comments concerning this draft guidance must be received by December 7, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Draft Guidance on Labeling for Laboratory Tests'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

The labeling and evaluation of laboratory test performance should compare a new product's test results to some appropriate and relevant diagnostic benchmark that can be used to correlate results from a new test with the clinical status or condition of individuals or patients for whom the test is intended to be used. Determination of the clinical status of patients whose specimens are used in an evaluation may be based on laboratory and/or clinical endpoints. FDA recognizes two major categories of endpoints for assessing performance of new laboratory assays: (1) ''True'' diagnostic state (patient clinical status or condition) or operational ''truth,'' and (2) laboratory equivalence where the test is characterized in terms of a

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.

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

Title of Information Collection: Request for Retirement Benefit Information;

Form No.: HCFA-R–285 (OMBı 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 Willinghan, 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.