Riverside Center is located within walking distance (0.8 mile) of the College Park station on Metrorail's Green Line. There is also Metrobus service and free shuttle service from the College Park Metro station to the Riverdale Center. For more walking, Metro, and driving information/directions, see http://www.aphis.usda.gov/biotech/direct.html or http://www.aphis.usda.gov/oa/aphismap.html.

The program agenda will be posted on the Internet at www.foodriskclearinghouse.umd.edu. Following the workshop, a transcript of the meeting will be posted at the same site.

Dated: August 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–22230 Filed 8–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1434]

Guidance for Industry on Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.'' The guidance provides recommendations to sponsors of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements to these applications who wish to request a waiver of in vivo bioavailability (BA) and bioequivalence (BE) studies for immediate-release solid oral dosage forms.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance 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 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–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5688.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.'' This guidance provides recommendations on when in vivo BA/BE studies may be waived for IND's, NDA's, and ANDA's during either the pre- or postapproval period.

Although in vivo documentation of BA and BE has been required for many drug products, in some cases FDA has allowed the use of in vitro methods for documenting BA and BE. As noted both at 21 CFR 320.22, ''Criteria for Waiver of Evidence of In Vivo Bioavailability or Bioequivalence,'' and at 21 CFR 320.24, ''Types of Evidence to Establish Bioavailability or Bioequivalence,'' many options exist to allow demonstration of BA and BE through in vitro methods. This guidance describes recommendations for requesting waivers of in vivo BA/BE studies on the basis of the solubility and intestinal permeability of the drug substance and dissolution characteristics of the drug product, based on a biopharmaceutics classification system.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on the waiver of in vivo BA and BE studies for immediate-release solid oral dosage forms based on a biopharmaceutics classification system. 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 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. The 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 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–22225 Filed 8–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–P–15A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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: Medicare Current Beneficiary Survey (MCBS): Rounds 29–37;

Form No.: HCFA–P–15A (OMB# 0938–0568);

Use: The MCBS is a continuous, multipurpose survey of a nationally representative sample of aged and disabled persons enrolled in Medicare. The survey provides a comprehensive

source of information on beneficiary characteristics, needs, utilization, and satisfaction with Medicare-related activities.;

Frequency: Other: 3 times a year;

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

Number of Respondents: 16,500;

Total Annual Responses: 49,500;

Total Annual Hours: 50,490.

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 (HCFA–P–15A), Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 22, 2000.

John P. Burke III,

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

[FR Doc. 00–22250 Filed 8–30–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

White House Initiative on Asian Americans and Pacific Islanders, President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to conduct a public meeting during the month of September 2000.

Name: President's Advisory Commission on Asian Americans and Pacific Islanders (AAPIs)

Date and Time:

September 18, 2000; 9:00 a.m.—7:00 p.m. EDT

September 19, 2000; 8:00 a.m.—3:00 p.m. EDT

Place:

On September 18, 2000, at: New York University, School of Law, Tishman Auditorium, 40 Washington Square South, New York, NY 10012

On September 19, 2000, at: New York University, School of Law, Greenberg Lounge, 40 Washington Square South, New York, NY 10012.

The meeting is open to the public.

The President's Advisory Commission on AAPIs will conduct a public meeting on September 18, 2000, from 9:00 a.m. to 7:00 p.m. EDT inclusive, and subsequent meeting on September 19, 2000, from 8:00 a.m. to 3:00 p.m. EDT inclusive.

Agenda items will include, but will not be limited to: testimony from community organizations and individuals; approval of July Commission meeting minutes; reports and recommendations from Commissioners and subcommittees; administrative tasks; deadlines; and upcoming events.

The purpose of the Commission is to advise the President on the issues facing Asian Americans and Pacific Islanders.

Requests to address the Commission should be made in writing and should include the name, address, telephone number, and business or professional affiliation of the interested party. Forms to request an opportunity to testify can be downloaded at: www.aapi.gov. Individuals or groups addressing similar issues are encouraged to combine comments and present through a single representative. The allocation of time for remarks may be adjusted to accommodate the level of expressed interest. Written requests should be faxed to (301) 443–0259.

Anyone who has interest in joining any portion of the meeting or who requires additional information about the Commission should contact: Mr. Tyson Nakashima, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD, 20857, Telephone (301) 443–2492. Anyone who requires special assistance, such as sign language interpretation, foreign language interpretation, or other reasonable accommodations, should contact Mr. Nakashima no later than September 8, 2000.

Dated: August 25, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00–22310 Filed 8–30–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 2000.

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: September 27, 2000; 9:00 a.m.—3:00 p.m.

Place: Ramada Inn Bethesda, 8400 Wisconsin Avenue, Bethesda, Maryland 20814.

The meeting is open to the public.

Purpose: The Advisory Committee shall (1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service (PHS) Act; and (2) prepare and submit to the Secretary, the Committee on Health, Education, Labor and Pensions (formerly the Committee on Labor and Human Resources) of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

Agenda: Discussion of the focus of the programs and activities authorized under section 747 of the PHS Act. Review of the work completed to date by the two workgroups formed during the April 20–21, 2000, meeting of the Advisory Committee.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Dr. Barbara Brookmyer, Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–1468, e-mail bbrookmyer@hrsa.gov. The web address for the Advisory Committee is http://158.72.83.3/bhpr/dm/new__advisory__committee__on__primar.htm.