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