is intended to provide recommendations to sponsors of NDA's, ANDA's, and supplements who intend to perform, during either the preapproval or postapproval period, bioavailability and bioequivalence studies for topical dermatological drug products.

The definitions of ''bioavailability'' and ''bioequivalence,'' the requirements for submitting such data in NDA's, ANDA's, and supplements, and the types of in vivo studies that are acceptable to establish bioavailability and bioequivalence are set forth in CFR part 320. These regulatory definitions and requirements reflect requirements in the Federal Food, Drug, and Cosmetic Act and other agency regulations.

Generally, bioavailability and bioequivalence of a drug product can be assessed through measurement of the active moiety(ies)/active ingredient(s) in an accessible biologic fluid such as blood, plasma, and urine. For some drug products, including topical dermatological drug products, it is not possible to use pharmacokinetic measurements of the active moiety(ies)/active ingredient(s) in blood, plasma, or urine to document bioequivalence because topical dermatological products generally do not produce measurable concentrations in extracutaneous biological fluids. This draft guidance document proposes other methods to establish bioavailability and bioequivalence, including the following types of studies: (1) Clinical studies; (2) pharmacodynamic studies; (3) dermatopharmacokinetic studies; and (4) in vitro studies. These approaches are discussed at 21 CFR 320.24, although these regulations do not provide specific methodologic approaches. In addition to general comments, FDA welcomes the submission of data that support or refute the use of any of these approaches, especially dermatopharmacokinetic approaches, in the documentation of bioavailiability and bioequivalence of topical dermatological drug products. FDA also welcomes the submission of relevant clinical, dermatopharmacokinetic, and in vitro release data for further evaluation of these approaches in the guidance. At some time following receipt of public comments and other information to this draft guidance, FDA intends to discuss the guidance and the public response to the guidance before a joint meeting of the Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee.

This draft guidance is a level 1 draft guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on bioavailability and bioequivalence approaches for topical dermatological drug products. 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 requirements of the applicable statute, regulations, or both.

Submit written requests for single copies of the draft 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. Requests should be identified with the docket number found in brackets in the heading of this document. Copies 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: June 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–SP–0001]

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

AGENCY: Health Care Financing Administration.

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:* Medicaid Post-Eligibility Preprint and Supporting Regulations in 42 CFR 430.10; *Form No.:* HCFA–SP–0001 (OMB# 0938–0673); *Use:* The post-eligibility preprint is part of the comprehensive statement that a State submits to show that it is meeting the requirements for Federal funding of its Medicaid program. It comprises part of each State's Plan which outlines the mandatory and optional aspects of a State's Medicaid program. Accurate submission of this information is necessary in order for States to receive Federal funding.; *Frequency:* On occasion; *Affected Public:* State, local or tribal government and Federal Government; *Number of Respondents:* 56; Total Annual Responses: 56; *Total Annual Hours:* 280.

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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 9, 1998.

John P. Burke III,

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

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