DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0381]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—NDA's; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 8, 1998, the comment period for a notice announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDA's'' that appeared in the **Federal Register** of April 8, 1998 (63 FR 17184). FDA is taking this action in response to a request for an extension and to allow interested parties additional time for review and to submit comments.

DATES: Written comments by July 8, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276; ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 8, 1998 (63 FR 17184), FDA's Center for Drug Evaluation and Research (CDER) published a notice announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDA's.'' The draft guidance is intended to assist applicants who wish to submit new drug applications (NDA's) in electronic format. Although voluntary, submissions of NDA's in electronic format should reduce the amount of paperwork for applicants and the agency. The April 8, 1998, notice invited interested persons to submit written comments on the draft guidance within 60 days.

On April 20, 1998, FDA received a letter from Pharmaceutical Research and Manufacturers of America, requesting that the agency extend the comment period on the draft guidance 90 days. In addition, in the **Federal Register** of June 1, 1998 (63 FR 29741), FDA's Center for Biologics Evaluation and Research (CBER) published a draft guidance for industry entitled ''Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/Establishment License Application (ELA) to the Center for Biologics Evaluation and Research.''

Because a number of NDA sponsors have expressed the wish to see the draft guidance become final as soon as possible and because the agency considers this to be a dynamic document, which will be updated in the future, the agency does not believe it is necessary to extend the comment period an additional 90 days. However, the agency agrees that an additional period will provide time for interested parties to review both CDER and CBER's guidances. Therefore, the agency is reopening the comment period for an additional 30 days, until July 8, 1998.

Interested persons may, on or before July 8, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 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 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–16140 Filed 6–17–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0388]

Draft Guidance for Industry on Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies.'' The draft guidance is intended to provide recommendations to sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements who intend to perform bioavailability and bioequivalence studies for topically applied dermatological drug products during either the preapproval or postapproval period. The agency is seeking comments on the draft guidance.

DATES: Written comments may be submitted on the draft guidance by August 17, 1998. General comments on the agency guidances are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' .

Submit written comments on this draft guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD. 20857. 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.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Topical Dermatological Drug Product NDA's and ANDA's—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies.'' The draft guidance

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.

[FR Doc. 98–16141 Filed 6–17–98; 8:45 am]

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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.

[FR Doc. 98–16148 Filed 6–17–98; 8:45 am]

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