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Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—NDA's; Reopening of Comment Period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Administration (FDA) is reopening until July 8, 1998, the comment period for a notice announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDA's'' that appeared in the **Federal Register** of April 8, 1998 (63 FR 17184).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ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.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(63 FR 17184), FDA's Center for Drug Evaluation and Research (CDER) published a notice announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDA's.'' The draft guidance is intended to assist applicants who wish to submit new drug applications (NDA's) in electronic format.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 The April 8, 1998, notice invited interested persons to submit written comments on the draft guidance within 60 days.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.

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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