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Dated: April 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0206]

Draft Guidance for Industry on Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs.'' Elsewhere in this issue of the **Federal Register**, FDA is announcing that all exocrine pancreatic insufficiency drug products are new drugs requiring approved new drug applications (NDAs) for marketing. This draft guidance is intended to aid sponsors of exocrine insufficiency drug products in submitting NDAs for the drug products.

DATES: Submit written or electronic comments on the draft guidance by June 28, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Monika Houstoun, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs.'' Elsewhere in this issue of the **Federal Register**, FDA is announcing that all exocrine pancreatic insufficiency drug products are new drugs. The document states that manufacturers who wish to continue to market these products must submit applications as required by section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and 21 CFR part 314. The document states that FDA is prepared to accept NDAs for these products, including applications submitted under section 505(b)(2) of the act. This draft guidance is intended to assist manufacturers of exocrine pancreatic insufficiency drug products in preparing and submitting documentation to meet NDA requirements for the drug products.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on issues concerning applications, including applications under section 505(b)(2) of the act, for exocrine pancreatic insufficiency 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two paper copies of any written comments, except that individuals may submit one paper 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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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