

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0206]

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 guidance for industry entitled “Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs.” This guidance is intended to assist manufacturers of exocrine pancreatic insufficiency drug products in preparing and submitting documentation to meet new drug application (NDA) requirements for the drug products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Maureen Dewey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5195, Silver Spring, MD 20993–0002, 301–796–0845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs.” On April 28, 2004 (69 FR 23410), FDA announced that all exocrine pancreatic insufficiency drug products are new drugs and 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 **Federal Register** announcement stated that FDA is prepared to accept NDAs for these products, including applications submitted under section 505(b)(2) of the act. This guidance is intended to assist manufacturers of currently marketed exocrine pancreatic insufficiency drug products in preparing and submitting documentation to meet NDA requirements for the drug products.

Also on April 28, 2004 (69 FR 23414), FDA announced the availability of the draft version of this guidance. A number of comments were received, and the agency considered them carefully as it finalized the guidance. Although the guidance has not changed substantially, the following changes are noteworthy: (1) In the Background section, the scope of the guidance was clarified; (2) in the Chemistry, Manufacturing, and Controls section, several items were further explained; (3) in the Nonclinical Pharmacology and Toxicology section, two points were additionally clarified; (4) in the Safety

subsection, the recommended dosage was updated; and (5) in the References section, two additional references were added and one reference was deleted.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on submitting NDAs 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 regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed 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. 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 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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