SUMMARY: The Food and Drug Administration (FDA) is planning a public meeting on FDA-regulated products containing nanotechnology materials. The purpose of the meeting will be to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices; whether there are scientific issues that should be addressed; and any other issues about which the regulated industry, academia and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

DATES AND TIMES: The public meeting will be held in mid-October 2006. Details on the date and time of the meeting will be provided in a subsequent **Federal Register** notice.

ADDRESSES: The public workshop will be held in the Washington, DC metropolitan area. The meeting address will be provided in a subsequent **Federal Register** notice and posted at *http://www.fda.gov/nanotechnology*.

Submit written comments 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*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For information about this document: Poppy Kendall, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *Poppy.Kendall@FDA.HHS.Gov*.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding a Public Meeting?

Nanotechnology is defined in a variety of ways. The National Nanotechnology Initiative (a U.S. Government research and development coordinating program) refers to nanotechnology as ''the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications'' (*http://www.nano.gov*). A nanometer is a billionth of a meter, and is approximately the width of 10 hydrogen atoms lined up side by side. (A human hair is about 80,000 nanometers in width. Deoxyribonucleic acid (DNA) is about 2.5 nanometers in width.)

Due to their small size and extremely high ratio of surface area to volume, nanotechnology materials often have chemical or physical properties that are different from those of their larger counterparts. Such differences include altered magnetic properties, altered electrical or optical activity, increased structural integrity, and increased chemical and biological activity. Because of these properties, nanotechnology materials have great potential for use in a vast array of products. Also because of some of their special properties, they may pose different safety issues than their larger counterparts. Of particular interest to FDA, nanotechnology materials may enable new developments in implants and prosthetics, drug delivery, and food processing, and may already be in use in some cosmetics and sunscreens. As part of its critical path initiative, FDA is interested in learning if there are opportunities for it to help overcome scientific hurdles that may be inhibiting the use of nanotechnology in medical product development.

We will be holding this meeting because we are interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices; whether there are scientific issues that should be addressed; and any other issues about which the regulated industry, academia and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

For more information about FDA's role regarding nanotechnology products, see our Web page at *http://www.fda.gov/nanotechnology*. We are announcing our plans now to hold a meeting to give ourselves and participants ample time to prepare.

II. How Can You Participate?

Details on registration and the meeting agenda will be provided in a subsequent **Federal Register** notice and at *http://www.fda.gov/nanotechnology*. To help us plan the logistics and agenda for the meeting, we would appreciate receiving expressions of interest from those planning on attending or presenting at the meeting, via e-mail or phone to Poppy Kendall (see **FOR FURTHER INFORMATION CONTACT**). We will attempt to obtain a venue and structure the meeting to accommodate the level of expressed interest and to address a range of topics, but will not begin the registration process until after publication of the subsequent **Federal Register** notice.

III. How Should You Send Comments on the Issues?

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). 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.

Dated: March 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5526 Filed 4–13–06; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. E6–5528 Filed 4–13–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0139]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Draft Revised Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft revised guidance for industry (#73) entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)'' VICH GL3(R). This draft revised guidance, which updates a guidance on the same topic for which a notice of availability was published in the **Federal Register** of October 12, 1999 (64 FR 55293) (the 1999 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised document is intended to provide guidance regarding the development of stability testing data new animal drug applications (referred to as registration applications in the guidance) submitted to the European Union (EU), Japan, and United States.

DATES: Submit written or electronic comments by May 15, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine, (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956, e-mail: *dennis.bensley@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.