

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0389]

DMB

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Certifier D. Hawkins

**Draft Guidance for Industry on Nonclinical Studies for Development of
Pharmaceutical Excipients; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Nonclinical Studies for Development of Pharmaceutical Excipients.” The draft guidance document provides guidance concerning development of safety profiles to support use of new excipients as components of drug or biological products. It is intended for use by reviewers within both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and by interested individuals in industry. The goals of this document are to foster and expedite the development of new excipients, communicate to industry current CDER and CBER thoughts pertaining to safety data needed to support excipient development, and increase uniformity within CDER and CBER on expectations for the nonclinical development of excipients.

DATES: Submit written or electronic comments on the draft guidance by [*date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and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 Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert E. Osterberg, Center for Drug Evaluation and Research (HFD-024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5482, or Martin D. Green, Center for Biologics Evaluation and Research (HFM-579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Nonclinical Studies for Development of Pharmaceutical Excipients.”

Excipients are potential toxicants. It is important to perform risk-benefit assessments on excipients for use in drug products and to establish permissible

limits for these compounds. These activities necessitate the availability of safety data. Consequently, there is a perception that development of new excipients is resource intensive. With proper planning, however, it is often possible to assess the toxicology of an excipient in a relatively efficient manner. Moreover, CDER and CBER recognize that existing human data for some excipients may substitute for nonclinical safety data, and use in previously approved products or GRAS status as a food additive will continue to receive consideration. This draft guidance describes the nonclinical data that should be generated to support the safety of an inactive ingredient in the amounts administered if adequate, relevant prior human use cannot be documented.

This 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 nonclinical studies for development of pharmaceutical excipients. 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.

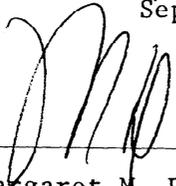
II. Comments

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 9/23/02
September 23, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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Dawn P. Hawkins