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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2002D-0389] (formerly 02D-0389)

#### Guidance for Industry on Nonclinical Studies for the Safety Evaluation 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 guidance for industry entitled "Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients." This document is intended to provide guidance on the types of toxicity information that FDA recommends be provided to the agency to support the use of new excipients in drug products. Previously, such information was not available to drug sponsors in a written document. This information should allow drug sponsors to determine if a potential new excipient is safe to use in 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, or the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Food and Drug Administration, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance

may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1-800-835-4709 or 301-827-1800. 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:

*For the Center for Drug Evaluation and Research:* Robert E. Osterberg, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2120, or

*For the Center for Biologics Evaluation and Research:* Mercedes A. Serabian, Center for Biologics Evaluation and Research (HFM-760), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6536.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients." This guidance addresses the safety testing of potential excipients to be used in pharmaceutical products. Not all excipients are inert substances; some have been shown to be potential toxicants. The Federal Food, Drug, and Cosmetic Act of 1938 (the act) was enacted after the tragedy of the elixir of sulfanilamide in 1937 in which an untested excipient was responsible for the death of many children who consumed the pharmaceutical. The act required manufacturers to perform safety testing of pharmaceuticals and submit new drug applications (NDAs) demonstrating safety before marketing. Since that time, the agency has become aware that certain other excipients used in commerce can cause serious toxicities in consumers of prescription and over-the-counter (OTC) drug products in the United States and other countries.

Some of the information used in developing this guidance was obtained during meetings involving the International Pharmaceutical Excipients Council, the United States Pharmacopeia, and the International Conference on Harmonisation. On October 2, 2002 (67 FR 61910), FDA announced the availability of a draft version of this guidance entitled "Nonclinical Studies for Development of Pharmaceutical Excipients." A number of comments were received, and the agency considered them carefully as it finalized the guidance.

This guidance describes the types of toxicity data that the agency uses in determining whether a potential new excipient is safe for use in human pharmaceuticals. It discusses recommended safety evaluations for excipients proposed for use in OTC and generic drug products, and describes testing strategies for pharmaceuticals proposed for short-term, intermediate, and long-term use. It also describes recommended excipient toxicity testing for pulmonary, injectable, and topical pharmaceuticals.

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 nonclinical studies for the safety evaluation 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Submit a single copy of electronic comments or two paper copies of 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. The guidance and received comments are available for public examination 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 <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: May 12, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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