

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0177]

RMS

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Certifier S. Purley

Guidance for Industry on Immunotoxicology Evaluation of Investigational
New Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

1132 10-1-02

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Immunotoxicology Evaluation of Investigational New Drugs." This guidance provides recommendations for sponsors of investigational new drugs (INDs) on what parameters to routinely assess in toxicology studies to determine effects on immune function, when to conduct additional immunotoxicity studies, and when additional mechanistic information could better characterize a given effect on the immune system.

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 Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://>

[/www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Hastings, Center for Drug Evaluation and Research (HFD-590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2489.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Immunotoxicology Evaluation of Investigational New Drugs.” The human immune system is a complex set of cells and organs that can be adversely affected by drugs. Impairment of the immune system can result in increased susceptibility to infections and tumors, allergic responses to drugs, autoimmune reactions, or other forms of immune system disease. Immunotoxicology studies can be conducted in animals to determine the potential of an investigational drug to adversely affect the immune system. This guidance provides advice on: (1) When to conduct immunotoxicology studies, (2) what types of effects can be observed in standard nonclinical toxicology studies that would indicate that a drug has immunotoxic potential, and (3) what types of studies could be useful in determining the nature of the immunotoxicity. It is expected that this guidance will provide sponsors with useful information for proper assessment of the immunotoxic potential of drugs.

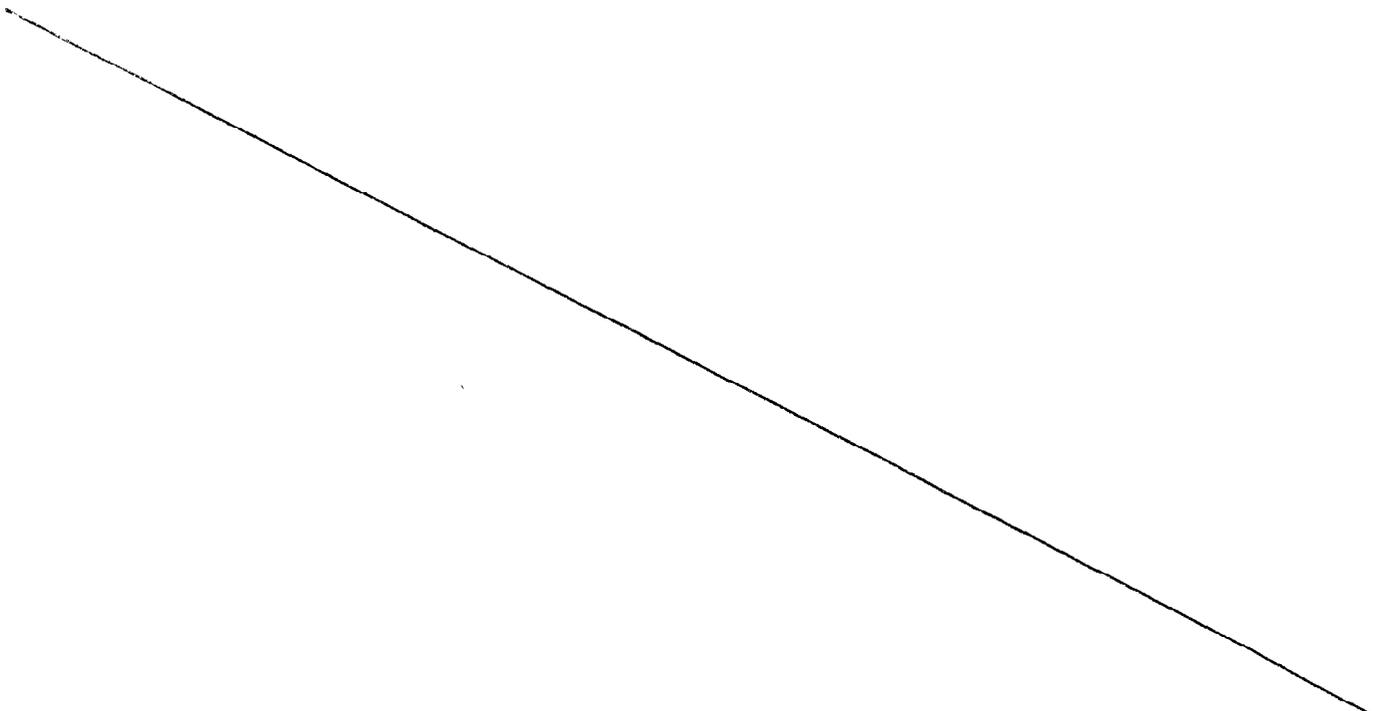
In the **Federal Register** of May 11, 2001 (66 FR 24145), FDA published a draft guidance entitled “Immunotoxicology Evaluation of Investigational New

Drugs.” The notice gave interested persons an opportunity to submit comments. Based on the comments, FDA has revised the guidance.

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 immunotoxicology evaluation of INDs. 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

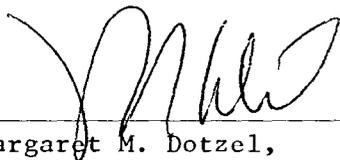
Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The 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 either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 10/28/02
October 28, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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