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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005D-0183]

Display Date	5-24-05
Publication Date	3-25-05
Officer	A. Corbin

**Draft Guidance for Industry on Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency.” This guidance is being issued to assist sponsors in developing and submitting nonclinical and clinical virology data, which are important to support clinical trials of antiviral agents. Nonclinical and clinical virology reports are essential components in the review of investigational antiviral drugs. The information in this guidance will facilitate the development of antiviral drug products.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Lisa K. Naeger, Center for Drug Evaluation and Research (HFD-530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20857, 301-827-2330; or Julian O'Rear, Center for Drug Evaluation and Research (HFD-530), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20857, 301-827-2330.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency.” The purpose of this guidance is to assist sponsors in the development of antiviral drug products and to serve as a starting point for understanding the nonclinical and clinical virology data important to support clinical trials of antiviral agents. This guidance focuses on nonclinical and clinical virology studies, which are essential components in the review of investigational antiviral drugs. Topics in this guidance include studies defining the mechanism of action, establishing specific antiviral activity of the investigative drug, providing data on the development of viral resistance to the investigational drug, and providing data identifying cross-resistance to approved drugs having the same target.

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 antiviral drug development;

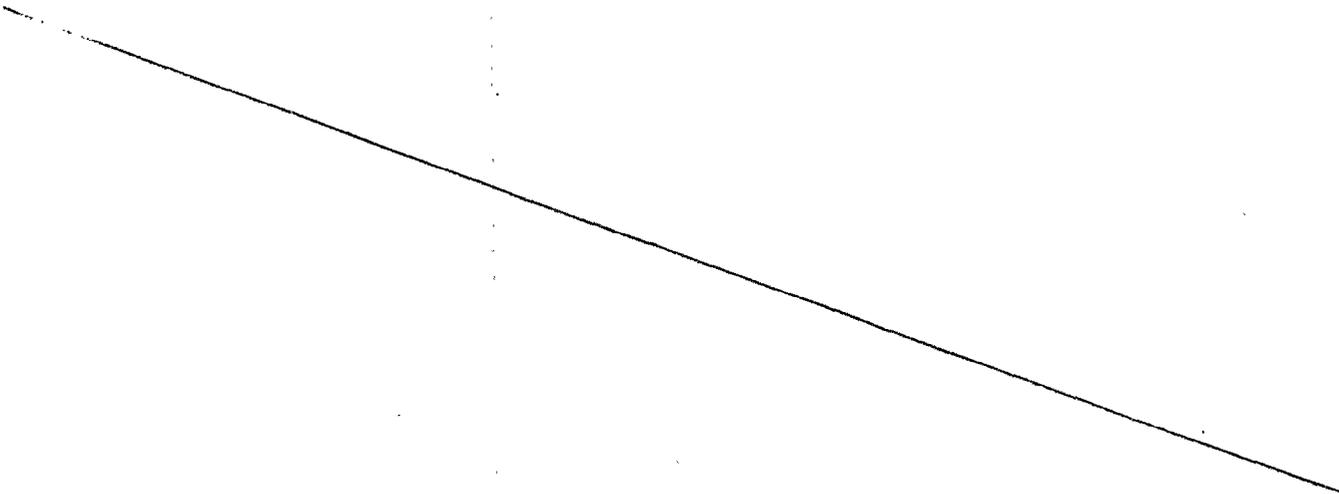
conducting virology studies and submitting the data to the agency. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## **II. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0014 (until January 31, 2006).

## **III. Comments**

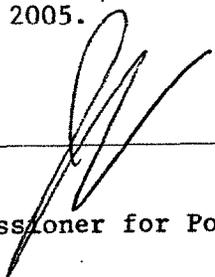
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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.



**IV. 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: 5/18/05  
May 18, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**

