

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0183]

DDM
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Coordinator D. Hawkins

**Guidance for Industry on Antiviral Product Development—Conducting and Submitting Virology Studies 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 guidance for industry entitled “Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency.” The purpose of this guidance is to assist sponsors in developing and submitting nonclinical and clinical virology data, which are important to support clinical trials of antiviral products. Nonclinical and clinical virology reports are essential components in the review of investigational antiviral products. The information in this guidance will facilitate the development of antiviral 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

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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:** Lisa K. Naeger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6367, Silver Spring, MD 20993-0002, 301-796-1500, or Julian O'Rear, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6368, Silver Spring, MD 20993-0002, 301-796-1500.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled "Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency." The purpose of this guidance is to assist sponsors in the development of antiviral products and to serve as a starting point for understanding the nonclinical and clinical virology data important to support clinical trials of antiviral products. This guidance focuses on nonclinical and clinical virology studies, which are essential components in the review of investigational antiviral products. Topics in this guidance include studies defining the mechanism of action, establishing specific antiviral activity of the investigational product, assessing the potential for antagonism of other antiviral products that might be used in combination with the investigational product, providing data on the development of viral resistance to the investigational product, and providing data that identify cross-resistance to approved products having the same target.

The guidance announced in this document finalizes the draft guidance entitled “Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency” that was announced in the **Federal Register** of May 25, 2005 (70 FR 30127). The sample formats that were included as appendixes in the draft guidance have been removed from the guidance and are now included as stand-alone documents. A fourth format for assisting sponsors in the submission of influenza data has been added. These sample formats will be updated as needed, and additional formats for other viruses may be provided.

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 conducting virology studies and submitting the data and reports 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.

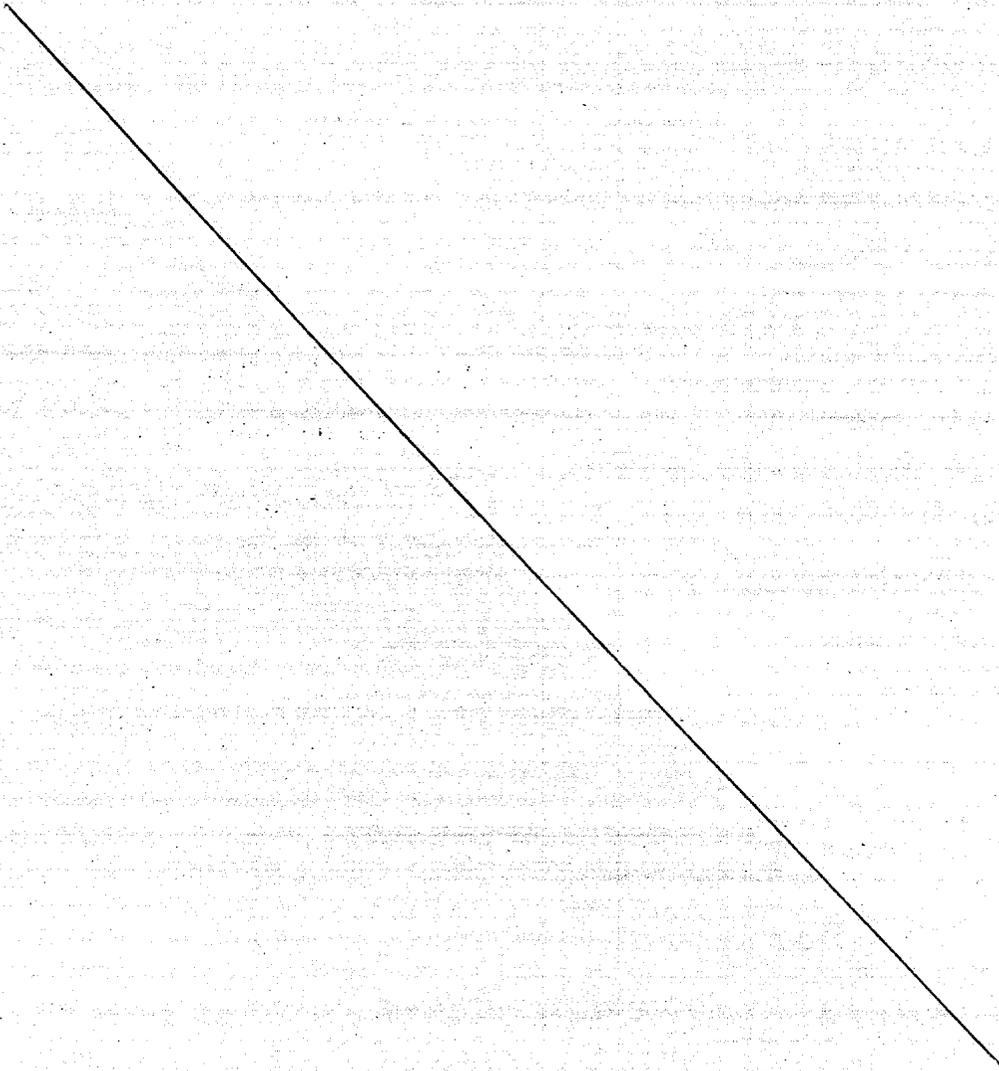
## **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information have been approved under OMB control number 0910–0014.

## **III. 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. The guidance and received comments may be seen 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: 5/23/06  
May 23, 2006.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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