

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0484]

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Certifier D. Hawkins

**Draft Guidance for Industry on the Role of Human Immunodeficiency Virus
Drug Resistance Testing in Antiretroviral Drug Development; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Role of HIV Drug Resistance Testing in Antiretroviral Drug Development." This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, the draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is also intended to serve as a focus for continued discussions among the Division of Antiviral Drug Product (DAVDP) in FDA's Center for Drug Evaluation and Research, pharmaceutical sponsors, the academic community, and the public.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.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ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing
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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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Jeffrey S. Murray, or Kimberly A. Struble Center for Drug Evaluation and Research (HFD-530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Role of HIV Drug Resistance Testing in Antiretroviral Drug Development.” This draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is based on the following: (1) A 2-day session of the Antiviral Drug Product advisory committee convened November 2 and 3, 1999, to address issues relating to HIV resistance testing; (2) the DAVDP’s experience with reviewing resistance data for antiretroviral drugs; and (3) input from pharmaceutical sponsors and the HIV community.

The draft guidance discusses the nonclinical studies (mechanism of action; antiviral activity in vitro; cytotoxicity/therapeutic index; and the effects of serum protein binding on antiviral activity) we recommend be completed prior to the initiation of phase 1 clinical studies in HIV-infected patients. In addition, the draft guidance addresses the use of resistance testing in the clinical phases of drug development and recommends the type of information that should be collected and the types of analyses that should be conducted

to characterize an antiretroviral's resistance profile. The draft guidance also reviews the role of resistance testing in initial activity and dose-finding, for study enrollment criteria, for background regimen selection, and to establish an indication. Included in this draft guidance are two appendices: (1) A template for submitting HIV resistance data and (2) information on the genetic threshold for resistance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the role of HIV resistance testing in antiretroviral drug development. 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 draft guidance. 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 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.

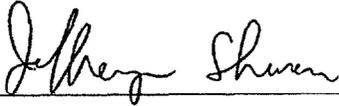
III. Paperwork Reduction Act of 1995

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 (PRA) (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under the OMB control number 0910–0014 (until January 31, 2006).

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: 11/19/04
November 19, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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