ACF program office	Program title	CFDA No.	Funding opportunity title and No.	Amount of cost share as % of total project cost	Acceptable types non-federal resources
Administration on Developmental Disabilities.	Developmental Disabilities Projects of National Significance.	93.631	Family Support 360 HHS–2008–ACF–ADD–DN–0009. Projects for Youth Information, Training and Resource Centers for Youth and Emerging Leaders with Developmental Disabilities HHS–2008–ACF–ADD–DN–0018.	25	Cash and In-Kind.

Historically, ACF has found that the imposition of a matching requirement on awards under these programs results in an increased level of community support and, often, a higher profile in the community. This can contribute to the success and sustainability of the project. The Fiscal Year 2008 funding opportunity announcements for each listed program will advise applicants on the percentage of funds that must be contributed through non-Federal resources, the composition of the match, and the merit of the match as a criterion in the competitive review. The amount and acceptable types of non-Federal resources allowed is not negotiable. However, matching may be provided as direct or indirect costs. The presence and composition of matching funds may be used as a criterion in evaluating the merits of an application during competitive review. Specific information related to the matching requirement and competitive review will be provided in the specific funding opportunity announcement. Unmatched Federal funds will be disallowed. Costs borne by matching contributions are subject to the rules governing allowability found under 45 CFR 74.23 and 45 CFR 92.24.

FOR FURTHER INFORMATION CONTACT: Melody Wayland, Office of Administration, Office of Financial Services Division of Grants Policy, 370 L'Enfant Promenade, SW., 6th Floor East, Washington, DC 20447, or by telephone at 202–401–5714 or *mwayland@acf.hhs.gov.*

Dated: October 24, 2007.

Curtis L. Coy,

Deputy Assistant Secretary for Administration, Administration for Children and Families.

[FR Doc. E7–21344 Filed 10–30–07; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0484]

Guidance for Industry on the Role of Human Immunodeficiency Virus 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 guidance for industry entitled ''Role of HIV Resistance Testing in Antiretroviral Drug Development.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, this guidance addresses the agency's current thinking regarding the role of HIV resistance testing during antiretroviral drug development and postmarketing. This guidance discusses important nonclinical studies that are recommended before the initiation of phase 1 clinical studies in HIV-infected patients. In addition, this guidance addresses the use of resistance testing in 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. This guidance finalizes the draft guidance published on November 29, 2004.

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 Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500, or

Kimberly Struble, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6374, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Role of HIV Resistance Testing in Antiretroviral Drug Development.'' This guidance is intended to assist sponsors in the clinical development of drugs for the treatment of HIV infection. Specifically, this guidance addresses the agency's current thinking regarding the role of HIV resistance testing during antiretroviral drug development and postmarketing. This guidance discusses the nonclinical studies (mechanism of action, antiviral activity in vitro, the effects of serum protein binding on antiviral activity, cytotoxicity and therapeutic index, and in vitro combination activity) that should be completed before the initiation of phase 1 clinical studies in HIV-infected patients. In addition, this guidance

addresses the use of resistance testing in 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. This guidance also is intended to serve as a focus for continued discussions among the Division of Antiviral Products, pharmaceutical sponsors, the academic community, and the public.

This guidance is based on a 2-day session of the Antiviral Drug Product Advisory Committee convened on November 2 and 3, 1999, to address issues relating to HIV resistance testing, the division's experience with reviewing resistance data for antiretroviral drugs, and input from pharmaceutical sponsors and the HIV community.

This guidance has been updated to address public comments on the draft version. The following significant changes were made to the guidance: (1) The inclusion of more details and clarification on the recommendations about the amount and type of nonclinical studies that should be conducted before phase 1 clinical studies, (2) the inclusion of more details and clarification regarding data collection and types of analyses for treatment-naïve and treatment-experienced patients, (3) the inclusion of additional details regarding exposure-response analyses, and (4) updated guidance for submitting HIV resistance data.

The guidance reviews the role of resistance testing in initial activity and dose-finding studies, for study enrollment criteria, and background regimen selection. The guidance also reviews the use of resistance data to establish an indication. This guidance includes an appendix that provides recommendations on how to submit HIV resistance data to FDA.

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 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. 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 in 21 CFR part 312 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. 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: October 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21403 Filed 10–30–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0049 (formerly Docket No. 02D–0049)]

Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for the public, FDA advisory committee members, and FDA staff entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers.'' This guidance is intended to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. The draft guidance announced in this notice supersedes FDA's ''Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees,'' dated January 2002.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by December 31, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, 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 telephone requests to 800–835–4709 or 301–827–1800.

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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers,'' dated October 2007. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA. FDA implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. The agency is authorized by statute to grant waivers to allow individuals with potentially conflicting financial