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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0112]

Display Date 8-18-04  
Publication Date 8-19-04  
Certifier J. Cooke

**Guidance for Industry on Independent Consultants for Biotechnology  
Clinical Trial Protocols; 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 document entitled "Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols," dated August 2004. The guidance document provides guidance to sponsors of clinical trials for certain products on when and how to request from FDA the engagement of an independent consultant to participate in the review of protocols for clinical studies intended to serve as the primary basis of claims of efficacy. This guidance document finalizes the draft guidance of the same title dated May 2003.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; or the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, cb0345

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MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER voice information system at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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*.

**FOR FURTHER INFORMATION CONTACT:** Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or Susan S. Johnson, Center for Drug Evaluation and Research, Office of New Drugs (HFD-20), 5515 Security Lane, suite 7215, Rockville, MD 20852, 301-594-3937.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols" dated August 2004. On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (PDUFA III). A letter from the Secretary of Health and Human Services (June 4, 2002), to Congress concerning PDUFA III included an addendum containing the performance goals and programs to which FDA committed as a means of facilitating the development and review of products subject to PDUFA III. One

commitment was for FDA to establish a program to allow sponsors of clinical trials for certain products to request that FDA engage an independent consultant to participate in the review of protocols for clinical studies that are intended to serve as the primary basis of claims of efficacy. This guidance document is intended to explain when and how a sponsor may take advantage of this program.

This guidance document finalizes the draft guidance document of the same title dated May 2003 (68 FR 24486, May 7, 2003). The 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 this topic. 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 or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this 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 the brackets in the heading of this document. A copy of the 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. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/ohrms/dockets/default.htm*, or *http://www.fda.gov/cder/guidance/index.htm*.

Dated: 8/11/04  
August 11, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

SENT  
07/11



[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

**BILLING CODE 4160-01-S**