

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D-0286]

Guidance for Industry: Class II Special Controls Guidance Document: In Vitro Human Immunodeficiency Virus Drug Resistance Genotype Assay; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay," dated August 2007. The guidance document provides a means by which in vitro human immunodeficiency virus (HIV) drug resistance genotype assays may comply with special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the in vitro HIV drug resistance genotype assay into class II (special controls). The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls," dated August 2001.

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

cb0222

2001D.0286

MAD 2

DDM
Display Date 8-7-07
Publication Date 8-8-07
Certifier Sker

Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay," dated August 2007. This guidance document was developed as a special control to support classification of the in vitro HIV drug resistance genotype assay from class III to class II (special controls). Also, it is intended for use in detecting HIV genomic mutations that confer resistance to specific antiretroviral drugs as an aid in monitoring and treating HIV infection.

In the **Federal Register** of August 29, 2001 (66 FR 45682), FDA announced the availability of the draft guidance entitled "Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls," dated August 2001. FDA received several comments

on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance entitled "Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls," dated August 2001.

II. Significance of the Guidance

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.

III. 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 807, subpart E (regulations governing premarket notification submissions) have been approved under OMB control number 0910-0120.

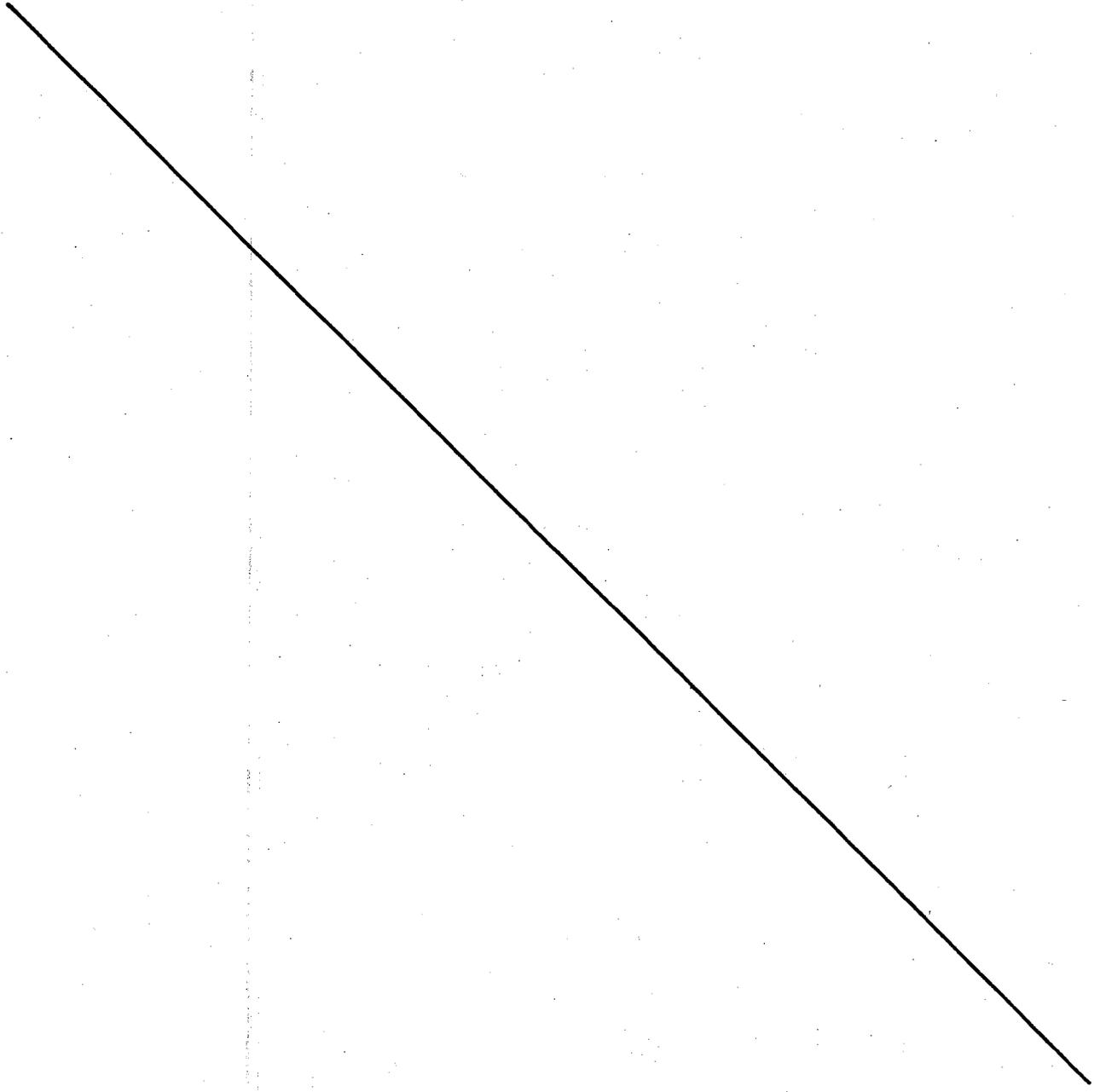
IV. Comments

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.

IV. Electronic Access

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



Dated: 8/2/07

August 2, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Sybil Roca