Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations'' dated April 2002.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the FDA'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 to the Division of Dockets Management written or electronic comments (see **ADDRESSES**) regarding the 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* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15472 Filed 8–7–07; 8:45 am]

BILLING CODE 4160–01–S

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 The guidance announced in this notice finalizes the draft guidance entitled ''Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls'' dated August 2001.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 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: August 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–15477 Filed 8–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revised information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the continued use of FEMA Form 95–22, Application for Admission, that is used to select participants for the U.S. Fire Administration (USFA) Executive Fire Officer Program (EFOP).

SUPPLEMENTARY INFORMATION: Public Law 93–498, the Fire Prevention and Control Act of 1974, created the National Fire Academy (NFA) which provides for courses and programs to train fire service personnel. Since 1985 USFA/NFA has sponsored and offered the EFOP, a professional development program for senior and executive level fire officers. The standard application form (FEMA Form 75–5, approved under OMB No. 1660–0005), used for all USFA/NFA courses, does not provide the sufficient information to select the most qualified applicants for the program. FEMA Form 95–22 will require a brief essay for questions specific to EFOP functions.

Collection of Information

Title: National Fire Academy Executive Fire Officer Program Application Form.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0021.

Form Numbers: FEMA Form 95–22, Application for Admission.

Abstract: The EFOP annually receives more applications from qualified applicants than there are program slots available. Additional information is required to objectively evaluate the applicant's writing capability, professional accomplishments, and analytical ability. This information along with supporting documentation are used to select the most qualified participants for the EFOP.

Affected Public: Individuals and households, and State, local or tribal governments.

Estimated Total Annual Burden Hours: 800 hours.

ANNUAL HOUR BURDEN

Data collection activity/instrument	No. of respondents (A)	Frequency of responses (B)	Hour burden per response (C)	Annual responses (D) = (A×B)	Total annual burden hours (C×D)
FEMA Form 95–22	400	1	1	400	400
Additional Documentation: Letter of Intent, Resume, Letter of Recommendation, Diploma Photocopy, Organizational Chart	400	1	1	400	400
Total	400	.....	.....	.....	800

Estimated Cost: Therefore; the estimated cost to respondents using wage rate categories is estimated to be $55,616.00 and the cost for postage and mailing to respondents is estimated to be $1,960.00 annually. The annual cost to respondents is estimated to total $57,576.00. The annual cost to the government for spending time reviewing FEMA Form 95–22 and additional documentation is estimated to be $1,836.00.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments must be submitted on or before October 9, 2007.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management and Privacy, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, 500 C. Street, SW., Room 609, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Chuck Burkell, (301) 447–1072 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov*.

Dated: July 31, 2007.

John A. Sharetts-Sullivan,

Director, Office of Records Management, Office of Management Directorate, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E7–15430 Filed 8–7–07; 8:45 am]

BILLING CODE 9110–17–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.