ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Developmental work—Household screener	14,535	1	3/60
Developmental work—Household screener & survey	6,151	1	28/60
Main implementation—Household screener	515,027	1	3/60
Main implementation—Household screener & survey	59,635	1	26/60

Dated: October 17, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer Centers for Disease Control and Prevention.

[FR Doc. E7–21208 Filed 10–26–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0393]

Draft Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility'' dated October 2007. The draft guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. In the **Federal Register** of March 9, 2005 (70 FR 11679), FDA withdrew the guidance document entitled ''Draft Guideline for the Validation of Blood Establishment Computer Systems,'' issued on September 28, 1993, and is issuing this guidance to reflect our current considerations on this topic.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 28, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, 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 draft document entitled ''Guidance for Industry: Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility'' dated October 2007. This draft guidance provides blood establishments with assistance in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. This draft guidance addresses blood establishment computer system validation rather than blood establishment computer software (BECS) validation. In the **Federal Register** of March 9, 2005, FDA withdrew the guidance document entitled ''Draft Guideline for the Validation of Blood Establishment Computer Systems,'' issued on September 28, 1993, and is issuing this guidance to reflect our current considerations on this topic.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 606.100(b) and 606.160 have been approved under OMB control number 0910–0116; those in 21 CFR 211.68 have been approved under OMB control number 0910–0139.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft 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 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.

IV. Electronic Access

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

Dated: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21268 Filed 10–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0047]

Guidance for Industry: Considerations for Plasmid Deoxyribonucleic Acid Vaccines for Infectious Disease Indications; 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: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications'' dated November 2007. The guidance document is intended to assist manufacturers and sponsors in the development of deoxyribonucleic acid (DNA) vaccines to prevent infectious diseases. The guidance supersedes the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996. In addition, the guidance announced in this notice finalizes the draft guidance of the same title dated February 2005.

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

ADDRESSES: 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: Joseph L. Okrasinski, Jr., 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: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications,'' dated November 2007. The guidance is intended to assist manufacturers and sponsors in the development of DNA vaccines to prevent infectious diseases. The document describes the manufacturing information that should be submitted to CBER for a new vaccine product for clinical study under an investigational new drug application (IND). Plasmid DNA products intended for non-infectious therapeutic indications are not addressed in the guidance. This guidance supersedes the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996. In addition, the guidance announced in this notice finalizes the draft guidance dated February 2005.

In the **Federal Register** of February 18, 2005 (70 FR 8378), FDA announced the availability of the draft guidance of the same title dated February 2005. FDA received several comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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. 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 collection of information mentioned in the guidance regarding the submission of manufacturer's information in an IND was approved under OMB control number 0910–0014.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments 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.

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: October 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21266 Filed 10–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2416–07; DHS Docket No. USCIS–2007–0052]

RIN–1615–ZA54

Termination of the Designation of Burundi for Temporary Protected Status; Automatic Extension of Employment Authorization Documentation for Burundi TPS Beneficiaries

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security (DHS).

ACTION: Notice.

SUMMARY: Following a review of country conditions and consultations with the Secretary of State and other appropriate Government agencies, the Secretary of Homeland Security has determined that the temporary protected status (TPS) designation for Burundi should be terminated. This termination will not take effect until May 2, 2009, to provide for an orderly transition. This Notice informs the public of the termination of the TPS designation for Burundi and sets forth procedures for nationals of Burundi (or aliens having no nationality who last habitually resided in Burundi)