are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22677 Filed 8–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2213]

Draft ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors;'' 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors.'' This draft guidance document, when finalized, is intended to provide guidance to blood establishments on invalidating donor test results based on control reagents required by the Clinical Laboratory Improvement Act of 1988 (CLIA). The implementation of additional quality control procedures that involve the use of external control reagents should enhance overall testing accuracy and blood safety.

DATES: Written comments on the draft guidance document may be submitted at any time, however, comments should be submitted by November 30, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors'' 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. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors.'' This draft guidance document would provide recommendations for blood establishments in integrating current CLIA requirements for invalidating donor test results based on CLIA required control reagents. When finalized, this draft guidance document would replace the January 3, 1994, guidance document entitled ''Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors.'' FDA has developed revised recommendations based on discussions held during the public meetings of the Blood Products Advisory Committee (BPAC) on September 26, 1996, and December 13, 1996, and additional discussions among the Centers for Disease Control and Prevention (CDC), Health Care Financing Administration (HCFA), and FDA. At this time, the draft guidance document is being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This document is being issued as a draft level 1 guidance document consistent with GGP's.

This draft guidance document represents the agency's current thinking with regard to the invalidation of test results based on the CLIA required external control reagents. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by November 30, 1999, to ensure adequate consideration in preparation of the final guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22801 Filed 8–31–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the

Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915–0172: Extension

The Health Resources and Services Administration (HRSA) proposes to revise the Guidance and Forms for the Application and Annual Report for the Maternal and Child Health Services Title V Block Grant Program. The guidance is used annually by the 50 States and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act, and in preparing the required annual report. The proposed revisions follow and build on extensive modifications made to the guidance and forms in 1997. The proposed revisions are of two types: (1) editorial and technical revisions based on the experiences of the States and jurisdictions in using the guidance and forms in 1998 and 1999; and, (2) the addition of a standard set of measures to be used in conducting the formal needs assessment required by Title V every five years. This needs assessment will be required of each State and jurisdiction in FY 2000.

The addition of the core set of measures for use in conducting the formal needs assessment follows discussions with State Maternal and Child Health Directors over the last two years. The changes incorporated in the 1997 revisions have been reflected in major changes in the Title V program, with much more emphasis on accountability and performance measurement as part of the performance partnership concept on which those changes were built. The inclusion now of standard measures for all States and jurisdictions to use in conducting the five-year needs assessment is a natural progression in the development of the Federal-State partnership process.

Following approval of the 1997 revisions, HRSA developed and instituted an automated electronic data collection and reporting system, the Title V Electronic Reporting Package (Title V ERP). The ERP has greatly reduced the burden on the States and jurisdictions, because it provides for automatic calculations of ratios, rates, and percentages, carries data over from year-to year, and assures that data used in multiple tables are entered only once. The ERP also provides for text entry, and facilitates the orderly printing of tables, text, and required appendices. As a result, even with the additional data that were incorporated, the expectation is that there will be a 33% reduction in the annual burden from previous levels. The estimated response burden is as follows:

Type of form	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
Application and Annual Report, with needs assessment*:				
States	50	1	450	22500
Jurisdictions	9	1	240	2160
Application and Annual Report, without needs assessment*:				
States	50	1	330	16500
Jurisdictions	9	1	133	1197

*The Application and Annual Report, with needs assessment, will be submitted in FY 2000. The Application and Annual Report, without needs assessment, will be submitted in FY 2001 and FY 2002. The average burden for the next three years is 20,018 hours.

The HRSA revision plan calls for draft versions of the new guidance to be sent to all Maternal and Child Health Directors in September, 1999. Copies will also be available to all other interested parties who request one from: Peter C. Van Dyck, M.D., M.P.H., Associate Administrator for Maternal and Child Health, Maternal and Child Health Bureau, Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. His phone number is (301) 443–2170.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 26, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–22802 Filed 8–31–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance on the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information;