

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0636]

Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*." FDA is issuing this guidance to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) intended for the detection of antibodies to *B. burgdorferi*. These devices are used to aid in the diagnosis of Lyme disease.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Prasad Rao, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 66, Rm. 5508, Silver Spring, MD 20993, 301-796-6203.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance recommends studies for establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi* in human serum, plasma, and blood. These devices are used to aid in the diagnosis of Lyme disease. This document does not apply to *B. burgdorferi* nucleic acid amplification assays. A manufacturer who intends to market an in vitro device for the detection of antibodies to *B. burgdorferi* must conform to the general controls of the Federal Food, Drug, and Cosmetic Act and, unless exempt, obtain premarket clearance or approval prior to marketing the device.

The draft guidance was announced in the **Federal Register** of January 5, 2011 (76 FR 570), and the comment period closed on April 5, 2011. No comments were received during the comment period.

II. Significance of Guidance

This 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 establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi*. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1721 to identify the guidance you are requesting.

IV. 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, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 42 CFR 493.15 have been approved under OMB control number 0910-0598; the collections of information 21 CFR 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-07085 Filed 3-27-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: 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, Pub. L. 104-13), the Health Resources

and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915-0204)—Extension

Abstract: The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine,

optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, state agencies, HEAL schools, and insurance companies, made new refinanced HEAL loans which are insured by the federal government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program monitors the federal liability and assists in default prevention activities.

The HEAL borrower, the borrower's physician, and the holder of the loan complete the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans; (2) pertinent information supplied by the certifying physician; (3) the physician's

certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death; and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim. No changes have been made to the current form.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Borrower	75	1	75	.08	6
Physician	75	1	75	.5	38
Holder of Loan	13	6	78	.17	13
Total	163	228	57

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: March 20, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013-07190 Filed 3-27-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Part C Early Intervention Services Grant Under the Ryan White HIV/AIDS Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for

persons living with HIV/AIDS, HRSA will provide a one-time noncompetitive Part C funds award to the University of Alabama at Birmingham (UAB).

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is \$1,283,907.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51

CFDA Number: 93.918.

Project period: The period of support for this award is 17 months, explained below in further detail.

Justification for the Exception To Competition: The Jefferson County Commission, Birmingham, AL (Grant Number: H76HA00098) announced the relinquishment of their Part C grant on January 31, 2013. To prevent a lapse in HIV medical care to the service area covered by that grant, grant funds of