DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0258]

Combined Functionality for Molecular Diagnostic Instruments; 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 ''Molecular Diagnostic Instruments with Combined Functions.'' This guidance document provides industry and Agency staff with FDA's current thinking on regulation of molecular diagnostic instruments that combine in a single instrument both approved/cleared device functions and device functions for which approval/clearance is not required, and on the type of information that FDA recommends that applicants include in a submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions.

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: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Molecular Diagnostic Instruments With Combined Functions'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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: Andrew Grove, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5515, Silver Spring, MD 20993–0002, 301–796–6198; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides industry and Agency staff with FDA's current thinking on regulation of molecular diagnostic instruments that combine in a single instrument both approved/cleared device functions and device functions for which approval/clearance is not required, and on the type of information that FDA recommends that applicants include in a submission for a molecular diagnostic instrument that measures or characterizes nucleic acid analytes and has combined functions. Molecular diagnostic instruments, for example, real-time thermocyclers, are critical components of certain in vitro diagnostic devices. They are often used to perform multiple unrelated assays, such as those that detect methicillin resistant *Staphylococcus aureus,* hepatitis C virus, and genetic markers of cystic fibrosis. These types of instruments cannot generally be approved/cleared alone, i.e., without an accompanying assay, because their safety and effectiveness cannot be evaluated without reference to the assays that they run and their defined performance parameters. However, the same instruments may also be used for additional purposes that do not require FDA approval or clearance, such as for basic scientific research. In the past, FDA has provided informal advice in response to individual inquiries regarding the permissibility of having functions for which approval/clearance is not required on an instrument intended to be used with approved/cleared in vitro diagnostic assays. This guidance is meant to communicate FDA's policy regarding molecular diagnostic instruments with combined functions.

This guidance applies to molecular diagnostic instruments that are medical devices used with assays that measure or characterize nucleic acid analytes, human or microbial, and that combine both approved/cleared and non-approved/non-cleared functions in a single instrument. This guidance applies to the instrument itself (hardware) as well as to any firmware or software intended to operate on or to control the instrument. This guidance also addresses software that is distributed as a stand alone device for use with an approved/cleared molecular diagnostic assay.

The guidance does not apply to instruments approved/cleared for use with assays that are intended to screen donors of blood and blood components, human cells, tissues, and cellular and tissue-based products, for communicable diseases. The document also does not apply to instruments approved/cleared for blood grouping. We encourage manufacturers wishing to market such instruments with combined functionality to contact the appropriate office in the Center for Biologics Evaluation and Research (CBER).

The recommendations in this guidance do not apply to assays and reagents. They are also not intended to change FDA's position regarding the marketing of Research Use Only and Investigational Use Only assays for clinical use.

The draft guidance was announced in the **Federal Register** of April 9, 2013 (78 FR 21128), and the comment period closed on July 8, 2013. Several comments were received during the comment period. We took the suggestions into consideration in revising and finalizing this guidance.

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 molecular diagnostic instruments with combined functions. 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 downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from

CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Molecular Diagnostic Instruments With Combined Functions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1763 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 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

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: November 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26694 Filed 11–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; HIV Study in Blood Donors From Five Chinese Regions (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** in Volume 79, June 12, 2014 on page 33764 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Chinese blood donation system. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health (NIH) may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301–435–0065, or Email your request, including your address to: *glynnsa@nhlbi.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: HIV Study in Blood Donors From Five Chinese Regions, 0925–0596 Reinstatement With Change, National Heart, Lung and Blood Institute (NHLBI)

Need and Use of Information Collection: This Study is a reinstatement with change of OMB Number: 0925–0596 expiration date, January 31, 2012. To better understand the diversifying and changing Human Immunodeficiency Virus (HIV) epidemic, and contemporary HIV risk factors, especially those associated with recent HIV infections, this HIV risk factor study in China is proposed as part of the Recipient Epidemiology and Donor Evaluation Study–III (REDS–III). The major objectives of the study will be to evaluate the proportion of blood donors in China who test positive for HIV and have acquired their infection recently or more remotely; the risk of releasing a blood product that contains HIV (HIV residual risk); and the risk factors associated with HIV infection in China. The study will also assess the frequency of distinct HIV–1 viral lineages and drug resistant mutations among HIV-positive blood donors. In 2011, there were 780,000 people infected with HIV in China and it is estimated that over 300,000 HIV infected people in China are not aware of their infection status. The large migrating population and the complexity of HIV transmission routes in China make it difficult to implement a comprehensive and effective national HIV control strategy. Risk factors for infections can change over time; thus, identifying factors that contribute to the recent spread of HIV in a broad cross-section of an otherwise unselected general population, such as blood donors, is highly important for obtaining a complete picture of the epidemiology of HIV infection in China. Because the pace of globalization means infections can cross borders easily, the study objectives have direct relevance for HIV control in the US and globally. Recent years have seen an increase in blood donations from repeat donors in most Chinese regions. This increase permits longer-term follow-up and testing of repeat donors which allow for calculation of new HIV infection rates and residual risks. The HIV data, for both recently and remotely acquired infections, from the proposed study will complement existing data on HIV risks obtained from general and high risk populations to provide comprehensive HIV surveillance data for China. This study will also monitor genetic characteristics of recently acquired infections through genotyping and drug resistance testing, thus serving a US and global public health imperative to monitor the genotypes of HIV that have recently been transmitted. For HIV, the additional monitoring of drug resistance patterns in newly acquired infection is critical to determine if currently available antiretroviral medicines are capable of combating infection. Genotyping and host response information are scientifically important not only to China, but to the US and other nations since they provide a broader global understanding of how to most effectively manage and potentially prevent HIV, for example through vaccine development. Efforts to develop vaccines funded by the National Institutes of Health and other US-based