DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0076] (formerly Docket No. 2007D–0387)

Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Studies—Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions." FDA is issuing this guidance to assist manufacturers in developing and conducting studies for IVD devices, particularly those exempt from most of the Investigational Device Exemption (IDE) regulations. The guidance explains data considerations that ultimately will affect the quality of the premarket submission. The draft of this guidance was issued October 25, 2007.

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 " In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development (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 that office in processing your request, or fax your request to CDRH at 301–847–8149. 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 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: Sally Hojvat, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5524, Silver Spring, MD 20993–0002, 301–796–5455; or

Stephen Ripley, 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

This guidance facilitates the movement of new IVD technology from the investigational stage to the marketing stage by providing information about the development and conduct of IVD studies that will be submitted to the agency to support premarket notifications and applications. Because many IVD studies are exempt from most of the IDE regulations at part 812 (21 CFR part 812) (§ 812.2(c)(3)), industry sponsors and FDA staff often have questions concerning the relevant requirements and appropriate methods for such studies. This guidance provides information about such studies as well as general information about the development, conduct, and responsibilities associated with all IVD studies. CDRH and CBER both have regulatory oversight of IVD devices. Information in this guidance is relevant to IVD devices regulated by either center under chapter I of title 21 of the Code of Federal Regulations, subchapter H.

In the **Federal Register** of October 25, 2007 (72 FR 60682), FDA announced the availability of the draft guidance. FDA received one comment regarding the use of investigational IVD devices in clinical drug trials. The comment addresses issues outside the scope of this guidance because this guidance makes recommendations for studies to support premarket notifications and approvals of IVD devices and does not address the use of investigational devices in clinical studies designed to evaluate new drug products.

FDA made several minor wording changes to the guidance document in order to improve clarity, however there are no significant, substantive changes.

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 "In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions." 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. To receive "In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions," you may either send an e-mail 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 1587 to identify the guidance you are requesting.

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* or the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*.

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 part 807 (21 CFR part 807), subpart E, including § 807.87, have been approved under OMB control no. 0910–0120; the collections of information in 21 CFR part 860 have been approved under OMB control no. 0910–0138; the collections of information in 21 CFR part 812 have been approved under OMB control no. 0910–0078; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control no. 0910–0130; the collections of information in 21 CFR part 803 have been approved under OMB control no. 0910–0437; the collections of information in 21 CFR part 810 have been approved under OMB control no. 0910–0432; the collections of information in part 814 (21 CFR part 814), subparts B and E, have been approved under OMB control no. 0910–0231; the collections of information in part 814, subpart H, have been approved under OMB control no. 0910–0332; the collections of information in 21 CFR part 820 have

been approved under OMB control no. 0910–0073; the collections of information in 21 CFR part 610 have been approved under OMB control nos. 0910–0116 and 0910–0338; and the collections of information in 21 CFR 809.10 have been approved under OMB control no. 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: June 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–15417 Filed 6–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Legislative Changes to Nursing Student Loan Program Authorized Under Title VIII of the Public Health Service Act

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (ACA), Public Law (Pub. L.) 111–148. Section 5202 of the ACA changes the Nursing Student Loan (NSL) program by: (1) Increasing the limits of loan funds to students; (2) revising the date of enrollment to be considered eligible to receive NSL funds; and (3) revising the date of loans eligible for partial loan cancellation.

SUPPLEMENTARY INFORMATION: The Nursing Student Loan (NSL) program was authorized by the Nurse Training Act of 1964 (Pub. L. 88–581) to alleviate the shortage of nursing personnel and to assure that no qualified student was denied the pursuit of a nursing career due to lack of financial resources. The NSL program provides long-term, low-interest loans to full-time and half-time students to help meet the cost of education. Students are eligible to apply for the NSL program if pursuing a course of study leading to a diploma in nursing, an associate or bachelor's degree in nursing or an equivalent degree, or a graduate degree in nursing. Below are details on how the ACA changes Sections 836(a), 836(b)(1), and 836(b)(3) of the Public Health Service Act, respectively, regarding the administration of the NSL program.

Loan Funding Limits

The ACA increases the maximum amount of NSL funding a student can receive. Previously, the total amount of NSL funds for any academic year could not exceed $2,500 in the case of any student except that, for the final 2 academic years of the program involved, such total could not exceed $4,000. With the legislative change, however, the new total amount of the loans for any academic year from NSL funds may not exceed $3,300 in the case of any student except that, for the final two academic years of the program involved, such total may not exceed $5,200.

Prior to the ACA, the aggregate of the NSL loans for all years from such funds was a maximum of $13,000 in the case of any student. Now, the aggregate of the loans for all years from such funds may not exceed $17,000 in the case of any student during fiscal years 2010 and 2011. After fiscal year 2011, the amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate of the loans. (Section 5202(a) of the ACA.)

Date of Enrollment

The ACA changes the date a student of financial need must be enrolled in a nursing program in order to be eligible to receive NSL funds. Previously an NSL loan could be made to a student of financial need who was enrolled after June 30, 1986. Now, an NSL loan can be made to a student of financial need who was enrolled after June 30, 2000. (Section 5202(b)(1) of the ACA.)

To be eligible, students are still also required to: (1) Pursue a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree, or a diploma in nursing, or a graduate degree in nursing and (2) be capable, in the opinion of the school, of maintaining good standing in such course of study.

Partial Loan Cancellation Date

Prior to the ACA, students who received NSL loans before September 29, 1979, could receive partial cancellation of their loans. Now, however, partial loan cancellation applies to loans received by students before September 29, 1995. (Section 5202(b)(2) of the ACA.)

A student who received such an NSL before September 29, 1995, can have an amount up to 85 percent of that nursing student loan (plus interest thereon) cancelled for full-time employment as a professional nurse in any public or non-profit private agency, institution, or organization, at the rate of 15 percent of the amount of such loan (plus interest) unpaid on the first day of such service for each of the first, second, and third complete year of such service, and 20 percent of such amount (plus interest) for each complete fourth and fifth year of such service. Employment as a professional nurse may include teaching in any of the fields of nurse training and serving as an administrator, supervisor, or consultant in any of the fields of nursing. Nursing experience prior to March 23, 2010 will not be considered in determining loan cancellation.

Dated: June 21, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–15421 Filed 6–24–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Host-Pathogen Interactions.

Date: August 2, 2010.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817.

Contact Person: Lynn Rust, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 3120, 6700B Rockledge