[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
[10] The numbers in this column have been rounded to the nearest whole number.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Annual disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
601.6(a)	1	20	20	0.33 (20 minutes)	7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The number is this column have been rounded to the nearest whole number.

Our estimated burden for the information collection reflects an overall increase of 105,948 hours and a corresponding decrease of 2,671 responses. We attribute this adjustment in the total hours to an increase in the number of submissions we have received under §§ 601.12(f)(4) and 601.45 and §§ 601.12(b)(1), (b)(3), and (e) over the last few years. We attribute the decrease in total annual responses to a decrease in responses received under §§ 601.12(a)(5) and 601.27(b) over the last few years.

Dated: September 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20328 Filed 9–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Luminex Corp., for the xMAP MultiFLEX Zika RNA Assay. FDA revoked this Authorization on July 3, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by Luminex Corp. by a letter dated June 18, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.

DATES: The Authorization is revoked as of July 3, 2019.

ADDRESSES: Submit written requests for single copies of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Pub. L. 108–276), and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On August 4, 2016, FDA issued an EUA to Luminex Corp. for the xMAP MultiFLEX Zika RNA Assay, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the **Federal Register** on October 28, 2016 (81 FR 75092), as required by section 564(h)(1) of the FD&C Act. In response to requests from Luminex Corp., the EUA was amended on January 7, 2017, and May 19, 2017. Under section 564(g)(2) of the FD&C Act, the Secretary of HHS may revoke an EUA if, among other things, the criteria for issuance are no longer met or other circumstances make such revocation appropriate to protect the public health or safety.

II. EUA Revocation Request for an In Vitro Diagnostic Device for Detection of the Zika Virus

On June 18, 2019, Luminex Corp. requested, and on July 3, 2019, FDA revoked, the EUA for the xMAP MultiFLEX Zika RNA Assay because the product will no longer be marketed, and these circumstances make revocation appropriate to protect the public health or safety.

III. Electronic Access

An electronic version of this document and the full text of the revocation are available on the internet at *https://www.regulations.gov/*.

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g) of the FD&C Act are met, FDA has revoked the EUA for Luminex Corp.'s xMAP MultiFLEX Zika RNA Assay. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

July 3, 2019

Ronald Dunn
Vice President Global Regulatory and Clinical Affairs
Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

Dear Mr. Dunn:

This letter is in response to Luminex Corporation's ("Luminex's") request dated June 18, 2019, that the Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA160015) for emergency use of the xMAP MultiFLEX Zika RNA Assay issued on August 4, 2016, and amended on January 7, 2017, and May 19, 2017. Luminex has decided to discontinue manufacture of the product and indicated that there are currently no lots of product in the field, all inventory is expired and Luminex will not manufacture additional lots.

Accordingly, FDA revokes EUA160015 for emergency use of the xMAP MultiFLEX Zika RNA Assay, under section 564(g)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3(g)(2)). The product will no longer be marketed, and these circumstances make revocation appropriate to protect the public health or safety. As of the date of this letter, the xMAP MultiFLEX Zika RNA Assay that was authorized by FDA for use by clinical laboratories for the qualitative detection of RNA from Zika virus is no longer authorized by FDA.

FDA encourages Luminex to instruct laboratories to discontinue use of and discard any remaining inventory immediately.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: September 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20327 Filed 9–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 21, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: The Teaching Health Center Graduate Medical Education (THCGME) Program Eligible Resident/Fellow FTE Chart OMB No. 0915–0367 − Extension

Abstract: THCGME Program, Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law 111–148. The Bipartisan Budget Act of 2018 (Pub. L. 115–123) provided continued funding for the THCGME Program. THCGME Program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. THCGME Program Eligible Resident/Fellow Full-Time Equivalents (FTE) Chart, published in the THCGME Notice of Funding Opportunity (NOFO), is a means for determining the number of eligible resident/fellow FTE's in an applicant's primary care residency program.

A 60-day notice was published in the **Federal Register** on June 19, 2019, vol. 84, No. 118; pp. 28559—60. There were no public comments.

Need and Proposed Use of the Information: THCGME Program Eligible Resident/Fellow FTE Chart requires applicants to provide: (a) Data related to the size and/or growth of the residency program over previous academic years, (b) the number of residents enrolled in the program during the baseline academic year, and (c) a projection of the program's proposed expansion over the next five academic years. It is imperative that applicants complete this chart to quantify the total supported residents. THCGME funding is used to support an expanded number of residents in a residency program, to establish a new residency training program, or to maintain filled positions at existing programs. Utilization of a chart to gather this important information has decreased the number of errors in the eligibility review process resulting in a more accurate review and funding process, and comports with the regulatory requirement imposed by 45 CFR 75.206(a) ''Standard application requirements, including forms for applying for HHS financial assistance, and state plans.''

Likely Respondents: Teaching Health Centers applying for THCGME funding through a THCGME NOFO process, which may include new applicants and existing awardees.

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 ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
THCGME Program Eligible Resident/Fellow FTE Chart	90	1	90	1	90
Total	90	.....	90	.....	90

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–20244 Filed 9–18–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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,