DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information relating to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Form FDA 356h.

DATES: Submit electronic or written comments on the collection of information by November 18, 2019.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 18, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 18, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–N–0578 for ''General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as confidential. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h

OMB Control Number 0910–0338—Extension

Under section 351 of the Public Health Services Act (PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimate for these regulations is included in the estimate under § 601.2(a) in table 1.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under 601.12(f)(4) in table 1.

Sections 601.12(b)(1) and (3), (c)(1), (3), and (5), and (d)(1) and (3) require applicants to follow specific procedures to submit information to FDA of any changes, in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (3) in table 1.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1) through (3) requires applicants to follow specific procedures to report certain labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under § 601.14, the content of labeling required in 21 CFR 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under §§ 601.2(a) (BLAs) and 601.12(f)(1) through (3) (labeling supplements and annual reports) in table 1.

Section 601.45 requires applicants of biological products for serious or life-threatening illnesses to submit to the Agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in 21 CFR parts 640, 660, and 680 that relate to information to be submitted in a license application or supplement for certain blood or allergenic products as follows: §§ 640.6; 640.17; 640.21(c); 640.22(c); 640.25(c); 640.56(c); 640.64(c); 640.74(a) and (b)(2); 660.51(a)(4); and 680.1(b)(2)(iii) and (d).

In table 1, the burden associated with the information collection requirements in the applicable regulations is included in the burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one subsection of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products including: § 640.74(b)(3) and (4) for Source Plasma Liquid; § 640.84(a) and (c) for Albumin; § 640.94(a) for Plasma Protein Fraction; § 660.2(c) for Antibody to Hepatitis B Surface Antigen; § 660.28(a), (b), and (c) for Blood Grouping Reagent; § 660.35(a) through (d) for Reagent Red Blood Cells; § 660.45 for Hepatitis B Surface Antigen; and § 660.55(a) and (b) for Anti-Human Globulin. The burden associated with the additional labeling requirements for

submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.65 or 21 CFR 809.10. Therefore, the burden estimates for these regulations are included in the estimate under §§ 610.60 through 610.65 in table 1. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485.

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a) until after licensing the product for use in adults. Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a) with adequate justification. The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a)–(c) to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70 rather than under this section.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of radiopharmaceuticals intended for in vivo administration for diagnostic and monitoring use. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 since these regulations deal with information to be provided in an application.

Section 601.70 (b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (Form FDA 2252 approved under OMB control number 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Sections 601.91 through 601.94 concern biological products for which human efficacy studies are not ethical or feasible. Section 601.91(b)(2) requires, in certain circumstances, such postmarking restrictions as are needed to ensure the safe use of the biological product. Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patients or potential patients for biological products approved under part 601, subpart H, when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under subpart H are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under subpart H to submit to the Agency for consideration during preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under §§ 601.91(b)(2) and 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR part 600 (OMB control number 0910–0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308). The burden estimate for § 601.91(b)(3) is included in the estimate under §§ 610.60 through 610.65.

Section 610.9(a) requires the applicant to present certain information, in the form of a license application or supplement to the application, for a modification of any particular test method or manufacturing process or the conditions which it is conducted under the biologics regulations. The burden estimate for § 610.9(a) is included in the estimate under §§ 601.2(a) and 601.12(b) and (c) in table 1.

Under § 610.15(d), the Director of CBER or the Director of CDER may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Manufacturers seeking approval of an exception or alternative must submit a request in writing with a brief statement describing the basis for the request and the supporting data.

Section 640.120 requires licensed establishments to submit a request for an exception or alternative to any requirement in the biologics regulations regarding blood, blood components, or blood products. For licensed establishments, a request for an exception or alternative must be submitted in accordance with § 601.12; therefore, the burden estimate for § 640.120 is included in the estimate under § 601.12(b) in table 1.

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials. Section 680.1(b)(3)(iv) requires manufacturers to notify FDA when certain diseases are detected in source materials.

Sections 600.15(b) and 610.53(b) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) (21 CFR 606.110(b)) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(b), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1.

Form FDA 356h, ''Application to Market a New or Abbreviated New Drug or Biologic for Human Use,'' is used for the applicable submissions to both CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA and helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. FDA

estimates an average of 24 hours to complete the application form which is included in the average burden per response. The estimated burden hours for nonbiological product submissions to CDER using FDA Form 356h are approved under OMB control number 0910–0001 (an estimated 16,650 submissions × 24 hours = 399,600 hours).

For advertisements and promotional labeling (*e.g.,* circulars, package labels, container labels, etc.) and labeling changes, manufacturers of licensed biological products may submit to CBER or CDER Form FDA 2253. Form FDA 2253 can also be submitted electronically. Form FDA 2253 is approved under OMB control number 0910–0001.

Respondents to this collection of information are manufacturers of biological products. Under table 1, the numbers of respondents are based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received in fiscal year 2018. Based on information obtained from FDA's database systems, there are an estimated 424 licensed biologics manufacturers. The total annual responses are based on the estimated number of submissions (*i.e.,* license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under section 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the estimated annual number of suspensions of a biologic license. In table 1, FDA is estimating one in case a suspension occurs.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use Form FDA 2253 to submit advertising and promotional labeling (which can include multiple pieces). Based on information obtained from FDA's database system, the estimate is based on the number of submissions received using Form FDA 2253 for advertising and promotional labeling.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study × 3 studies) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately 2 to 4 studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under § 610.15(d), FDA has received no submissions since the implementation of the final rule in April 2011. Therefore, FDA is estimating one respondent and one annual request to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials under § 610.15(d).

There were a total of 3,398 amendments to an unapproved application or supplement and resubmissions submitted using Form FDA 356h.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [10]
601.2(a),[2] 610.60 through 610.65 [3]	356h	36	1.28	46	860	39,560
601.5(a)	NA	8	1.13	9	0.33 (20 minutes)	3
601.6(a)	NA	1	1	1	0.33 (20 minutes)	1
601.12(a)(5)	NA	430	4.158	1,788	1	1,788
601.12(b)(1)/(b)(3)/(e) [4]	356h [2]	166	4.843	804	80	64,320
601.12(c)(1)/(c)(3) [5]	356h [2]	149	4.58	682	50	34,100
601.12(c)(5)	356h [2]	7	1.14	8	50	400
601.12(d)(1)/(d)(3) [6]/(f)(3) [8]	356h [2]	245	3.575	876	24	21,024
601.12(f)(1) [7]	2253	65	3.169	206	40	8,240
601.12(f)(2) [7]	2253	43	2.05	88	20	1,760
601.12(f)(4)/601.45 [9]	2253	134	145.86	19,545	10	195,450
601.27(b)	NA	12	1.08	13	24	312
601.27(c)	NA	2	1	2	8	16
601.70(b) and (d)/601.28	2252	65	3.169	206	24	4,944
610.15(d)	NA	1	1	1	1	1
680.1(c)	NA	9	1	9	2	18
680.1(b)(3)(iv)	NA	1	1	1	2	2
Amendments/Resubmissions	356h	136	24.985	3,398	20	67,960
Total						439,899

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.9(a), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).

[3] The reporting requirements under §§ 601.93(b)(3), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a), (b), and (c), 660.35(a) through (d), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.

[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.53(b), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).

[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).

[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.