U.S. FOOD & DRUG ADMINISTRATION

February 22, 2024

Tara Viviani, RAC
Senior Director, Molecular Regulatory Affairs
Luminex Corporation
12212 Technology Blvd.
Austin, TX 78727

Re: Revocation of EUA201881

Dear Tara Viviani:
This letter is in response to the request from Luminex Corporation, in a letter dated February 19, 2024, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay issued on July 16, 2020, and amended on September 23, 2021, and March 9, 2022. Luminex Corporation indicated that they have discontinued manufacture of the authorized product and requested that the EUA be withdrawn. FDA understands that as of the date of this letter there are no viable xMAP SARS-CoV-2 Multi-Antigen IgG Assay reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Luminex Corporation has requested that FDA withdraw the EUA for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201881 for the xMAP SARS-CoV-2 Multi-Antigen IgG Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the xMAP SARS-CoV-2 Multi-Antigen IgG Assay is no longer authorized for emergency use by FDA.

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

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Cc: Jennifer Svoboda, Manager, Regulatory Affairs, Luminex Corporation

Dated: March 15, 2024.
Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2024–05980 Filed 3–20–24; 8:45 am]
BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0802]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 reporting, recordkeeping, and third-party disclosure burden associated with the veterinary feed directive regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by May 20, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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–2024–N–0802 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive.'' 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 *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://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.govinfo.gov/content/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 *https://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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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.

Veterinary Feed Directive—21 CFR 558.6

OMB Control Number 0910–0363—Revision

This information collection helps support implementation of FDA statutory and regulatory requirements. Section 504 of the Federal Food, Drug, and Cosmetic Act (FD&C) (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called veterinary feed directive (VFD) drugs. Our VFD regulation is set forth at § 558.6 (21 CFR 558.6). VFD drugs are new animal drugs, intended for use in or on animal feed, which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional

practice. An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

Distributors of medicated feed containing VFD drugs notify FDA of their intent to distribute such feed via U.S. Postal mail, email, or fax and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs. Veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor. For third-party disclosures, FDA regulation requires that veterinarians include specific information on the VFD. A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgment letter from the receiving distributor (consignee) before the feed is shipped.

We developed the guidance document ''Guidance for Industry (GFI) #233 Veterinary Feed Directive Common Format Questions and Answers'' (September 2016) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-233-veterinary-feed-directive-common-format-questions-and-answers*) to provide guidance concerning the elements that must be included on the VFD and the elements that may be included on the VFD as described in § 558.6. The guidance also provides examples that illustrate how a common VFD format might appear. We plan to revise the information collection to incorporate this guidance document as an instrument. Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible. We will use the information collected to assess compliance with the VFD regulation. The required reporting, recordkeeping, and third-party disclosures provide assurance that the medicated feeds will be safe and effective for their labeled conditions of use and that edible products from treated animals will be free of unsafe drug residues.

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(c)(5) requires a distributor to notify FDA prior to the first time it distributes a VFD feed.	112	1	112	0.12 (7 minutes)	13
558.6(c)(6) requires a distributor to notify FDA within 30 days of any change in ownership, business name, or business address.	239	1	239	0.12 (7 minutes)	29
Total	351				42

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

The number of respondents is based on the average number of notifications we have received over the past 3 years.

B. Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(a)(4) and (c)(3), (4), and (8); requires recordkeeping by veterinarians, producers, and distributors to maintain their copy of the VFD Order, their receipt and distribution records, and their manufacturing records and acknowledgement letters, if applicable, for 2 years.	30,800	219.03	6,746,096	0.02 (1 minute) ..	134,922

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

FDA's guidance document, ''GFI #213 New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' (December 2013) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*) describes a voluntary process wherein sponsors of new animal drugs used in and on animal feed and in water changed the marketing status of these drugs from over-the-counter to VFD. As a result of this voluntary process, which occurred in January 2017, the number of establishments distributing feeds containing VFD drugs increased, as well as the number of veterinarians issuing VFDs, and the number of food animal producers using VFD medicated feed. Thus, based on the current number of mixed practice veterinarians and the number of food animal veterinarians listed on the American Veterinary Medical Association's website, we have increased the number of recordkeepers for veterinarians and producers.

Additionally, based on our program experience, we have decreased the number of records per recordkeeper, as we believe the previous numbers were too high. The burden we attribute to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents.

In addition to the recordkeeping requirement under § 558.6(c)(3), if a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with 21 CFR part 225 and

such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, ''Current Good Manufacturing Practice Regulations for Medicated Feed.''

C. Third-Party Disclosure Requirements

Description of Respondents: Food Animal Veterinarians, VFD Feed Distributors, and Clients.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)(v) and (b)(7)(ix); requires veterinarians to disclose information on a VFD ...	5,278	40	211,120	0.12 (7 minutes)	25,334
558.6(c)(8); requires acknowledgment letter from one distributor to another	2,422	5	12,110	0.12 (7 minutes)	1,453
Total	7,700	.....	.....	.....	26,787

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

Based on program experience, we believe the original number of third-party disclosures estimate was too high and have decreased the number of disclosures per respondent. The VFD regulation also contains several labeling provisions. These labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*).

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the VFD regulations and updated data. As a result, the total burden for the information collection has decreased 39,387 hours since the last OMB approval.

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05986 Filed 3–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0972]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

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 reporting and recordkeeping requirements of our regulations implementing the Federal Import Milk Act (FIMA).

DATES: Either electronic or written comments on the collection of information must be submitted by May 20, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

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- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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'').

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- 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–2024–N–0972 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act.'' 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 *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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