in TAP processes and operations. All TAP Pilot participants will make up the potential group of respondents for the interviews, however, FDA intends to interview only a stratified sample of all potential participants. In addition, around 60 manufacturers will be interviewed after completing an application to participate.

TAP Pilot Participant Pulse Surveys

FDA seeks to obtain quantitative satisfaction ratings and free-response data from TAP Pilot participants using a 2-question survey deployed closely following TAP Pilot interactions (*e.g.,* teleconferences, written feedback). The same pulse survey will be administered after each interaction. The purpose of these surveys is to measure level of satisfaction with the interaction and allow for an opportunity for participants to provide feedback regarding the interaction. Manufacturers will also be surveyed one additional time per year just to gauge satisfaction over time with their experience interacting with FDA. This equates to 254 burden hours per year (rounded).

To supplement the data collection methods listed above, FDA would like to obtain interaction-related data by passively observing meetings among FDA staff, applicants, and external stakeholders. We plan to use an internal structured observational meeting form or checklist to standardize data collection. The purpose of these observations is to evaluate meeting attendance, level of collaboration, and the degree to which key processes and activities are being adhered. Data collected may also support identification of improvement opportunities to the TAP Pilot. We do not intend to actively collect this information from meeting participants directly (*e.g.,* by asking questions or collecting documents).

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05970 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–1091]

Revocation of Six Authorizations of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Life Technologies Corp. (a legal entity of Thermo Fisher Scientific, Inc.), for the TaqPath COVID–19 Pooling Kit; Bio-Rad Laboratories, Inc., for the Reliance SARS–CoV–2 RT–PCR Assay Kit; Revvity, Inc., (on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics)), for the PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit; bioMérieux SA for the VIDAS SARS–CoV–2 IgM kit; bioMérieux SA for the VIDAS SARS–CoV–2 IgG kit; and Luminex Corp. for the xMAP SARS–CoV–2 Multi-Antigen IgG Assay. FDA revoked the Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The Authorization for the Life Technologies Corp.'s (a legal entity of Thermo Fisher Scientific, Inc.) TaqPath COVID–19 Pooling Kit is revoked as of January 16, 2024. The Authorization for the Bio-Rad Laboratories, Inc.'s Reliance SARS–CoV–2 RT–PCR Assay Kit is revoked as of January 16, 2024. The Authorization for the Revvity, Inc.'s (on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics)) PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit is revoked as of January 30, 2024. The Authorization for the bioMérieux SA's VIDAS SARS–CoV–2 IgM kit is revoked as of January 31, 2024. The Authorization for the bioMérieux SA's VIDAS SARS–CoV–2 IgG kit is revoked as of January 31, 2024. The Authorization for the Luminex Corp.'s xMAP SARS–CoV–2 Multi-Antigen IgG Assay is revoked as of February 22, 2024.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (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, radiological, or nuclear agent or 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 May 25, 2021, FDA issued the Authorization to Life Technologies Corp. (a legal entity of Thermo Fisher Scientific, Inc.), for the TaqPath COVID–19 Pooling Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040 at 39043), as required by section 564(h)(1) of the FD&C Act.

On January 15, 2021, FDA issued the Authorization to Bio-Rad Laboratories, Inc., for the Reliance SARS–CoV–2 RT–PCR Assay Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21549 at 21751), as required by section 564(h)(1) of the FD&C Act.

On April 12, 2021, FDA issued the Authorization to PerkinElmer Genomics, (Revvity, Inc. (Revvity Omics, a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics)) for the PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on July 23, 2021 (86 FR 39040 at 39042), as required by section 564(h)(1) of the FD&C Act.

On August 6, 2020, FDA issued the Authorization to bioMérieux SA for the VIDAS SARS–CoV–2 IgM kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346 at 74350), as required by section 564(h)(1) of the FD&C Act.

On August 6, 2020, FDA issued the Authorization to bioMérieux SA for the

VIDAS SARS–CoV–2 IgG kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346 at 74350), as required by section 564(h)(1) of the FD&C Act.

On July 16, 2020, FDA issued the Authorization to Luminex Corp. for the xMAP SARS–CoV–2 Multi-Antigen IgG Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346 at 74350), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorizations Revocation Requests

In a request received by FDA on November 13, 2023, Life Technologies Corp. (a legal entity of Thermo Fisher Scientific, Inc.), requested the revocation of, and on January 16, 2024, FDA revoked, the Authorization for the Life Technologies Corp.'s (a legal entity of Thermo Fisher Scientific, Inc.) TaqPath COVID–19 Pooling Kit. Because Life Technologies Corp. notified FDA that they are no longer commercially supporting the TaqPath COVID–19 Pooling Kit and requested FDA revoke the Authorization for Life Technologies Corp.'s TaqPath COVID–19 Pooling Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 7, 2024, Bio-Rad Laboratories, Inc., requested the revocation of, and on January 16, 2024, FDA revoked, the Authorization for Bio-Rad Laboratories, Inc.'s Reliance SARS–CoV–2 RT–PCR Assay Kit. Because Bio-Rad Laboratories, Inc. notified FDA that they have ceased U.S. distribution of the Bio-Rad Reliance SARS–CoV–2 RT–PCR Assay Kit and requested FDA revoke the Authorization for Bio-Rad Laboratories, Inc.'s Reliance SARS–CoV–2 RT–PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 19, 2024, Revvity, Inc. (on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics)), requested the revocation of, and on January 30, 2024, FDA revoked, the Authorization for the Revvity, Inc.'s PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit. Because Revvity, Inc. notified FDA that they have discontinued use of the PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit at the Revvity Omics laboratory, and requested FDA revoke the Authorization for Revvity, Inc.'s PerkinElmer SARS–CoV–2 RT–qPCR Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 22, 2024, bioMérieux SA, requested the revocation of, and on January 31, 2024, FDA revoked, the Authorization for the bioMérieux SA's VIDAS SARS–CoV–2 IgM kit. Because bioMérieux SA notified FDA that they will no longer commercially support the authorized product, and requested FDA revoke the Authorization for bioMérieux SA's VIDAS SARS–CoV–2 IgM kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on January 22, 2024, bioMérieux SA, requested the revocation of, and on January 31, 2024, FDA revoked, the Authorization for the bioMérieux SA's VIDAS SARS–CoV–2 IgG kit. Because bioMérieux SA notified FDA that they will no longer commercially support the authorized product, and requested FDA revoke the Authorization for bioMérieux SA's VIDAS SARS–CoV–2 IgG kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

In a request received by FDA on February 19, 2024, Luminex Corp., requested the withdrawal of, and on February 22, 2024, FDA revoked, the Authorization for the Luminex Corp.'s xMAP SARS–CoV–2 Multi-Antigen IgG Assay. Because Luminex Corp. notified FDA that they have discontinued the manufacture of the authorized product, and requested FDA revoke the Authorization for Luminex Corp.'s 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.

III. Electronic Access

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

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Life Technologies Corp.'s (a legal entity of Thermo Fisher Scientific, Inc.) TaqPath COVID–19 Pooling Kit, Bio-Rad Laboratories, Inc.'s Reliance SARS–CoV–2 RT–PCR Assay Kit, Revvity, Inc.'s (on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics)) PerkinElmer SARS–CoV–2 RT-qPCR Reagent Kit, bioMérieux SA's VIDAS SARS–CoV–2 IgM kit, bioMérieux SA's VIDAS SARS–CoV–2 IgG kit, and Luminex Corp.'s xMAP SARS–CoV–2 Multi-Antigen IgG Assay. The revocations in their entirety follow and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

January 16, 2024

Stacy Drakousis,
Sr. Manager, Regulatory Affairs
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008

Re: Revocation of EUA202924

Dear Stacy Drakousis:

This letter is in response to the request from Life Technologies Corporation (a legal entity of Thermo Fisher Scientific, Inc.), in a letter dated November 13, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the TaqPath COVID-19 Pooling Kit issued on May 25, 2021, and amended on September 23, 2021, and May 31, 2023. Thermo Fisher Scientific, Inc. indicated that they are no longer commercially supporting the TaqPath COVID-19 Pooling Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable TaqPath COVID-19 Pooling Kit 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 Thermo Fisher Scientific, Inc. has requested that FDA revoke the EUA for the TaqPath COVID-19 Pooling Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202924 for the TaqPath COVID-19 Pooling Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath COVID-19 Pooling Kit 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

U.S. FOOD & DRUG ADMINISTRATION

January 16, 2024

Elizabeth Platt, EdD, MS
V.P., Regulatory & Clinical Affairs
Bio-Rad Laboratories, Inc.
4000 Alfred Nobel Drive
Hercules, CA 94547

Re: Revocation of EUA202864

Dear Dr. Platt:

This letter is in response to the request from Bio-Rad Laboratories, Inc., in a letter dated January 7, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit issued on January 15, 2021, and amended on May 11, 2021, September 23, 2021, and October 25, 2022. Bio-Rad Laboratories, Inc. indicated that they have ceased United States (U.S.) distribution of the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit and requested that the EUA be revoked. FDA understands that as of the date of this letter there will no longer be any viable Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit reagents remaining in distribution in the U.S.

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 Bio-Rad Laboratories, Inc. has requested that FDA revoke the EUA for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202864 for the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay Kit 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

U.S. FOOD & DRUG ADMINISTRATION

January 30, 2024

Lisa Vershave
Regulatory Affairs Manager
Revvity, Inc.
940 Winter Street
Waltham, MA 02451

Re: Revocation of EUA202494

Dear Lisa Vershave:

This letter is in response to the request from Revvity, Inc., on behalf of Revvity Omics (a Revvity, Inc. company that was a rebranding of PerkinElmer Genomics) in an email dated January 19, 2024, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit issued on April 12, 2021, and amended on September 23, 2021. Revvity, Inc. indicated that as of the date of this letter they have discontinued use of the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit at the Revvity Omics (formally PerkinElmer Genomics) laboratory located in Pittsburgh.

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 Revvity, Inc. has requested that FDA revoke the EUA for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202494 for the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit 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

U.S. FOOD & DRUG ADMINISTRATION

January 31, 2024

Laura Zani
Regulatory Affairs Specialist
bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Étoile, France

Re: Revocation of EUA201554

Dear Laura Zani:

This letter is in response to the request from bioMérieux SA in a letter dated January 22, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the VIDAS SARS-CoV-2 IgM kit issued on August 6, 2020, reissued on March 11, 2021, and amended on September 23, 2021. BioMérieux SA indicated that they will no longer commercially support the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable VIDAS SARS-CoV-2 IgM 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 bioMérieux SA has requested that FDA revoke the EUA for the VIDAS SARS-CoV-2 IgM, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201554 for the VIDAS SARS-CoV-2 IgM, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIDAS SARS-CoV-2 IgM 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

U.S. FOOD & DRUG ADMINISTRATION

January 31, 2024

Laura Zani
Regulatory Affairs Specialist
bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Étoile, France

Re: Revocation of EUA201553

Dear Laura Zani:

This letter is in response to the request from bioMérieux SA in a letter dated January 22, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the VIDAS SARS-CoV-2 IgG kit issued on August 6, 2020, reissued on March 11, 2021, and amended on September 23, 2021. BioMérieux SA indicated that they will no longer commercially support the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable VIDAS SARS-CoV-2 IgG 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 bioMérieux SA has requested that FDA revoke the EUA for the VIDAS SARS-CoV-2 IgG, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201553 for the VIDAS SARS-CoV-2 IgG, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the VIDAS SARS-CoV-2 IgG 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

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