vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: March 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05969 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–1201]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Total Product Life Cycle Advisory Program Pilot

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collections associated with Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot.

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–1201 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Total Product Life Cycle Advisory Program Pilot.'' 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: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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 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.

Total Product Life Cycle (TPLC) Advisory Program (TAP) Pilot

OMB Control Number 0910–NEW

This information collection supports the TPLC Advisory Program (TAP) Pilot. FDA's Center for Devices and Radiological Health (CDRH) launched the voluntary TAP Pilot in 2023 (87 FR 61605; October 12, 2022). The TAP Pilot is one of the commitments agreed to between FDA and industry as part of the reauthorization of the Medical Device User Fee Amendments for fiscal year (FY) 2023 through FY 2027 [1] (MDUFA V).[2] The long-term vision for TAP is to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance. Over the course of MDUFA V, the voluntary TAP Pilot is intended to demonstrate the feasibility and benefits of process improvements to FDA's early interactions with participants and of FDA's facilitation of interactions between participants and stakeholders that support the vision for TAP.

A key goal of the TAP Pilot is to improve various aspects of medical device development and to increase the predictability and reduce the time from concept to commercialization, in part, by facilitating robust engagement early in the process with FDA, industry, and key stakeholders.

The MDUFA V commitment letter states that FDA will conduct an assessment of the overall outcomes of the TAP Pilot that will include a participant satisfaction survey and quantitative and qualitative success metrics that include, but are not limited to: (1) the extent to which FDA is successful at meeting the quantitative goals described in V.J.3.b [3] of the MDUFA V commitment letter; (2) participant satisfaction with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA; (3) participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and (4) an overall assessment of the outcomes of the TAP Pilot and opportunities for improvement.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
TAP Pilot Manufacturers Requesting to Participate.	225	1	225	0.25 (15 minutes)	56
Satisfaction Survey Participants	200	2	400	0.33 (20 minutes)	132
TAP Pilot Participant Interviews and Passive Observations.	60	1	60	1	60
Pulse Survey Participants	200	1	200	0.03 (2 minutes)	6
Total [2]					254

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals may not sum due to rounding.

Application To Participate in TAP Pilot Program

FDA is developing a software portal mechanism through which sponsors interested in device enrollment into the TAP Pilot program can request enrollment. FDA estimates that approximately 225 manufacturers will submit a request to participate in the TAP Pilot.

TAP Pilot Participant Satisfaction Survey

This assessment includes a participant survey utilizing quantitative and qualitative success metrics. Data collected under this survey will help FDA evaluate the TAP Pilot. Specifically, FDA seeks to evaluate:

- participant satisfaction with the timeliness, frequency, quality, and efficiency of interactions with and written feedback from FDA;
- participant satisfaction with the timeliness, frequency, quality, and efficiency of voluntary interactions with non-FDA stakeholders facilitated by FDA (if utilized); and
- other outcomes of the TAP Pilot and opportunities for improvement.

Any sponsors who participate in the TAP Pilot will be invited to take the survey. We estimate that approximately 200 manufacturers will qualify and therefore will be surveyed 2 times per year.

TAP Pilot Participant Interviews

In support of qualitative success metrics and sentiments around the operation of the TAP Pilot, FDA seeks to conduct interviews with TAP Pilot participants, including applicants and external stakeholders, such as professional societies, payers, and patient advocacy groups. The purpose of these interviews is to better understand individual participants' experiences in the TAP Pilot. Data collected in these interviews will help FDA understand the impact of the TAP Pilot and potential opportunities for improvement

[1] MDUFA V spans from FY 2023 through FY 2027. The fiscal year runs from October 1 through September 30, so FY 2023 runs from October 1, 2022, through September 30, 2023.

[2] For more information on FDA's TAP Pilot, see the TAP Pilot web page at: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap*.

[3] See section V.J.3.b of the MDUFA V commitment letter, MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027, available at: *https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v*.

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]

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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