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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Fleischer, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0809, *Steven.Fleischer@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 30, 2022 (87 FR 73560), FDA announced the availability of draft GFI #276, entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs,'' giving interested persons until January 30, 2023, to comment on the draft guidance. In response to a request for an extension, the comment period was extended to May 1, 2023 (88 FR 3744). FDA received eight comment submissions on the draft guidance, some with numerous discrete comments within the submission; all comments were considered as the guidance was finalized. We clarified our discussion and recommendations related to geographic locations, laboratory dose confirmation studies, and field effectiveness studies. We also clarified that the recommendations in this guidance are based on current technology and veterinary epidemiology, including available diagnostic methodologies. Individuals are encouraged to discuss deviations from these recommendations with FDA, especially as advances in veterinary medicine related to heartworm disease, including disease epidemiology, isolate characterization, or diagnostic testing are identified.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13922 Filed 6–25–24; 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; Submission for Office of Management and Budget Review; 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 or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 26, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is Voluntary Total Product Life Cycle Advisory Program Pilot. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910–NEW

This information collection supports the TPLC TAP. FDA's Center for Devices and Radiological Health 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.

In the **Federal Register** of March 21, 2024 (89 FR 20209), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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	60	1	60	1	60
Passive Observations	100	1	100	0	0
Pulse Survey Participants	105	1	105	0.03 (2 minutes)	3
Total [2]					251

[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.

Upon further review of the proposed information collection, we updated the burden table to include a distinct line item for Passive Observations for the TAP Pilot and to adjust the estimated number of respondents expected for the Pulse Survey.

FDA estimates that approximately 225 manufacturers will submit a request to participate in the TAP Pilot. Any sponsors who participate in the TAP Pilot will be invited to take the survey. As such, there is no sampling plan; the whole population of TAP Pilot participants will be invited to participate. TAP Pilot participants consist of both applicants and external stakeholders, such as professional societies, payers, and patient advocacy groups.

We estimate that approximately 200 manufacturers will qualify and therefore will be surveyed 2 times per year. In addition, around 60 manufacturers will be interviewed after completing an application to participate. Manufacturers will also be surveyed 1 additional time per year just to gage satisfaction over time with their experience interacting with FDA. This equates to 251 burden hours per year (rounded).

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 submit an application to join.

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.

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 in TAP processes and operations. All

[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*.

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.

TAP Pilot Passive Observations

FDA would like to obtain interaction-related data by passively observing meetings between FDA staff, applicants, and external stakeholders. Passive observations impose no burden on respondents, as they are solely conducted by FDA staff without requiring any input or action from the respondents. We plan to use a 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 information from meeting participants directly (*e.g.,* by asking questions or collecting documents).

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.

Dated: June 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13961 Filed 6–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0263]

Agency Information Collection Request (ICR). 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 26, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV.* When submitting comments or requesting information, please include the document identifier 0990–0263–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form.

Type of Collection: Renewal, 3-year extension with non-substantive changes for the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form OMB No. 0990–0263 Office of the Assistant Secretary for Health, Office for Human Research Protections

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension with non-substantive changes of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990–0263.

The information collected on the form is to provide a simplified method for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103 for assurance identification and institutional review board (IRB) certification and declare exemption status. Non-substantive changes include adding instructions that, if additional assurances apply, those details can be indicated in the ''Comments'' section and clarifying that the form element for IRB expiration date does not apply to all projects.

Likely Respondents: Institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule), which is codified for HHS at 45 CFR part 46, subpart A.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	13,000	2	0.5	13,000