Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB Control No. 0985–0029]

Agency Information Collection Activities: Proposed Collection; Public Comment Request of the State Councils on Developmental Disabilities (Councils) State Plan

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a 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 Information Collection (IC) Revision solicits comments on the information collection requirements relating to the Developmental Disabilities State Plan OMB control number 0985–0029.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 30, 2023.

ADDRESSES: Submit comments on the collection of information via email to *Sara.Newell-Perez@acl.hhs.gov* or to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Sara Newell-Perez.

FOR FURTHER INFORMATION CONTACT: Sara Newell-Perez, 202–795–7413 or *Sara.Newell-Perez@acl.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. The PRA 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, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

The State Councils on Developmental Disabilities (Councils) are authorized in Subtitle B, of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), as amended, [42 U.S.C. 15001 *et seq.*] (The DD Act). The DD Act requires Councils to submit a five-year State plan. Section 124(a) [42 U.S.C. 15024(a)], states that: *Any State desiring to receive assistance under this subtitle shall submit to the Secretary, and obtain approval of, a 5-year strategic State plan under this section.* The DD Act regulations outlines additional guiding requirements in 45 CFR part 1326.30(a), which states that: *In order to receive Federal financial assistance under this subpart, each State Developmental Disabilities Council must prepare and submit to the Secretary, and have in effect, a State plan which meets the requirements of sections 122 and 124 of the Act (42 U.S.C. 6022 and 6024) and these regulations.*

The Council is responsible for the development, and submission of the State plan as well as implementation of the activities described in the plan. The Council updates the Sate plan annually during the five years. The State plan provides information on individuals with developmental disabilities in the State, and a description of the services available to them and their families. The State plan sets forth the goals and specific objectives to be achieved by the State Council in pursuing systems change and capacity building that result in empowering people with developmental disabilities to lead independent lives within the community. It describes State priorities, strategies, and actions, and the allocation of funds to meet these goals and objectives. Additionally, the data collected in the State plan and submitted to ACL is also used to comply with the GPRA Modernization Act of 2010 (GPRAMA).

The State Plan is used in three ways. First, it provides a framework for citizens, State governments, and other key stakeholder to provide input and comments to help shape the goals and objectives during the development stage. Secondly, it is used by each Council as a planning document to operationalize its goals and strategies. Finally, it provides information the Department needs for monitoring and providing technical assistance to ensure the Council is compliant.

This is a revision of a currently approved information collect that expires March 30, 2023. To ensure the DD Council State plan is consistent with the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, ACL intends to determine whether sexual orientation and gender identity (SOGI) data elements need to be adapted prior to adding them to ensure accessibility of the questions for individuals with intellectual and developmental disabilities.

The proposed data collection tool may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Total annual burden hours
State Councils on Developmental Disabilities State plan	56	1	367	20,522
Total	56	1	367	20,522

Dated: November 23, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2899]

Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #276 entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' This draft guidance is intended for sponsors and potential sponsors who may be interested in pursuing approval of investigational new animal drugs for the prevention of heartworm disease in dogs. The draft guidance provides recommendations for the effectiveness evaluation of drugs indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* in dogs. These recommendations should be read in conjunction with related Agency Veterinary International Conference on Harmonization (VICH) guidance documents and are intended to provide additional detail to elements of study design and interpretation under the recommendations laid out in the VICH guidances.

DATES: Submit either electronic or written comments on the draft guidance by January 30, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2022–D–2899 for ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' Received comments 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.

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