the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the information collection requirements for the Process Evaluation of the Aging Network and its Return on Investment [OMB #0985–New].

DATES: Submit written comments on the collection of information by March 10, 2022.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Caryn Bruyere, Office of Performance and Evaluation. Administration for Community Living Telephone: 202–795–7393 Email: *caryn.bruyere@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The Administration for Community Living (ACL) is requesting approval to collect data for the Process Evaluation of the Aging Network and its Return on Investment [OMB #0985–New]. Many older adults have unmet health care and social service needs, which require coordinated care across a range of services, including access to nutritious meals, transportation, preventive health care, home and community-based care, social interaction, support for family caregivers, and advocacy to help maintain older adults' safety, dignity, and legal rights. This proposed data collection for the Process Evaluation of the Aging Network and its Return on Investment is intended to provide timely information on, (1) how agencies in the Aging Network collaborate to serve older adults and family caregivers, and (2) how agencies measure the effectiveness of their efforts with the goal of strengthening their reach and impact. Through this data collection ACL will investigate how states differ in their network structure, how agencies work together, and potential strategies for evaluating return on investments (ROI) of ACL programs.

The Process Evaluation of the Aging Network and its Return on Investment will include: (1) A census of agencies in the Aging Network, and (2) key informant interviews with agencies that are evaluating ROI. The survey seeks to collect data from all State Units on Aging (SUAs), Area Agencies on Aging (AAAs) (including some Aging and Disability Resource Centers), and Older Americans Act Title VI Native American tribal organizations. Surveying these organizations will help ACL understand how and with whom agencies in the network collaborate to address the needs of older adults and family caregivers, partnerships that have formed or expanded because of COVID–19, and how agencies measure the effectiveness and ROI of their various programs. The study will also include key informant interviews with a subset of 10 agencies that responded to the survey whose responses indicate that their agency is evaluating ROI. The data collection team will ask in-depth questions about the costs and benefits included in ROI calculations, successes and challenges to evaluating ROI, and lessons learned that could benefit other agencies seeking to conduct their own assessment of ROI.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on, August 30, 2021 in 86 FR 48428. There were no substantive public comments received during the 60-day FRN.

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

The proposed data collection estimates the average burden per response to be 0.17 hours for the Aging Network survey. The average burden per response for the key informant interviews estimated as 1 hour.

Data collection activity	Annual number of respondents	Number of responses per respondent	Total number of responses	Average burden per response (in hours)	Annual estimated burden hours
Aging Network survey	864	1	864	0.25	216
Key informant interview guide	10	1	10	1	10
Total	874	Varies	874	0.26 (weighted mean).	226

Dated: February 3, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022–02578 Filed 2–7–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1051]

Clinical Pharmacology Considerations for Antibody-Drug Conjugates; 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 entitled ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates,'' which provides recommendations for the development of antibody-drug conjugates (ADCs). Specifically, this guidance addresses the FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs). Currently, there are

no FDA guidances outlining the clinical pharmacology considerations for antibody-drug conjugates. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 9, 2022 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–2021–D–1051 for ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kimberly Maxfield, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 209903, 301–348–1978, *Kimberly.Maxfield@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' An ADC is a type of therapeutic biologic product that is composed of a small-molecule moiety and an antibody moiety conjugated together by a chemical linker. An antibody or antibody fragment carrier is selected or engineered against a specific antigen of interest present on the target, which is ideally unique to the disease state being treated (*e.g.,* a tumor-specific antigen). In general, when the antibody or antibody fragment binds to its target antigen, the ADC is internalized through physiological mechanisms (*e.g.,* endocytosis), at which point the small-molecule drug or payload moiety is released either upon exposure to the low pH of the lysosome or by degradation of the antibody/linker by lysosomal enzymes. The released small-molecule drug then exerts its effect in the targeted cell (*e.g.,* the cells expressing the specific antigen of interest) while, ideally, minimizing the effect on healthy cells (*e.g.,* cells that do not express the specific antigen of interest).

ADCs combine the selectivity of an antibody or antibody fragment with the potency of a small molecule. Therefore, development of ADCs requires careful consideration of the differences between the clinical pharmacology of the antibody or antibody fragment and the small molecule. This draft guidance addresses FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and DDIs. Although

this draft guidance is primarily based on FDA's experience with ADCs for oncology indications, the principles discussed in this guidance are also generally applicable to the development of ADCs for other indications.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' 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 draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively. In addition, the submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; and the collections of information regarding good laboratory practice in 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/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: February 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02604 Filed 2–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by March 10, 2022.

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 OMB control number for this information collection is 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Prescription Drug User Fee Program

OMB Control Number 0910–0297—Revision

This information collection supports implementation of the Food and Drug Administration Prescription Drug User Fee Act (PDUFA) program. PDUFA was enacted in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new NDAs and BLAs submitted to FDA for review. We have established a PDUFA page on our website at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/* that includes resources and information regarding PDUFA topics at FDA.

Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. To assist respondents in this regard, we developed Form FDA 3397 entitled ''PDUFA Cover Sheet.'' Additional information and associated instructions may be found on our website at *https://www.fda.gov/industry/fda-user-fee-programs.* The cover sheet (Form FDA 3397) need not be submitted for certain FDA-regulated products, *e.g.,* generic drugs, and whole blood and blood components for transfusion. The list of exempted products is included under the instructions to Form FDA 3397. Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, refund, and reconsideration requests. We developed the guidance document entitled ''Guidance for Industry—Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products,'' and Form FDA 3971 (Small Business Waiver and Refund Request), which can be found on our website at *https://www.fda.gov/media/131797/download.*

We are revising the collection to include our current commitment goals, as set forth in the document ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' also found on our website at *https://www.fda.gov/media/99140/download.* PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. The commitment goals represent the product of FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to meeting these goals and to continuous