Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Recommended States List (Form L–11)	60	10.0	0.33	198
Child Advocate Referral (Form L–12A)-Respondents	300	19.0	0.25	1,425
Child Advocate Referral (Form L–12A)-Recordkeepers	1	5,601.0	0.33	1,848
Acknowledgment of Receipt of Legal Resource Guide (LRG–4)-Unaccompanied Children	121,669	2.0	0.25	60,835
Acknowledgment of Receipt of Legal Resource Guide (LRG–4)-Care Providers	300	817.0	0.25	61,275
Notice of Administrative Review (Form P–18)	200	1.0	.83	166
Estimated Annual Burden Hours Total				259,664

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–24588 Filed 10–23–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4470]

Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Sales and Distribution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our reporting and recordkeeping requirements for antimicrobial animal drug sales and distribution.

DATES: Either electronic or written comments on the collection of information must be submitted by December 23, 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 December 23, 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–4470 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Sales and Distribution.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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, including each proposed extension of an existing 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.

Antimicrobial Animal Drug Sales and Distribution—21 CFR 514.87

OMB Control Number 0910–0659—Extension

This information collection helps support implementation of Agency statutory and regulatory requirements regarding new animal drugs containing an antimicrobial active ingredient. Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) to submit to FDA an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. Sponsors are also required to maintain distribution records for their animal drug products, including separate information for each month of the calendar year, under section 512(l)(3) of the FD&C Act. These provisions were enacted to assist FDA in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance.

Section 514.87 of our regulations (21 CFR 514.87) codifies the reporting requirements established in the FD&C Act. Sponsors submit antimicrobial animal drug sales and distribution reports to us on Form FDA 3744. Each report must specify: (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. Each report must also provide a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in cattle, swine, chickens, or turkeys for such species that appear on the approved label.

Description of Respondents: Animal drug manufacturers (sponsors). Respondents include individuals and the private sector (for-profit businesses).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Paper Submission	1	1	1	62	62
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Electronic Submission	15	10.1	152	52	7,904
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Paper Submission	2	3.5	7	2	14
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Electronic Submission	10	17.9	179	2	358
Total					8,338

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate sponsors with active applications, who submit an annual antimicrobial annual drug sales and distribution report on paper, will spend 62 hours to assemble the necessary information, prepare, and submit to FDA. We estimate sponsors with active applications, who submit an annual antimicrobial animal drug sales and distribution report electronically, will spend 52 hours to assemble the

necessary information, prepare, and submit to FDA. We estimate that sponsors with inactive applications will spend 2 hours preparing their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	23	1	23	2	46

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA's current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910–0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910–0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 46 hours for further compliance with section 512(l)(3), as detailed in table 2.

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the antimicrobial animal drug distribution reports program. Our estimated burden for the information collection reflects a decrease of 54 burden hours and a corresponding decrease of 27 total annual responses. We attribute this to respondents who submitted by paper in previous years and are now reporting electronically.

Dated: October 18, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24721 Filed 10–23–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3768]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adherence Potential and Patient Preference in Prescription Drug Promotion

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.

DATES: Submit written comments (including recommendations) on the collection of information by November 25, 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 ''Adherence Potential and Patient Preference in Prescription Drug Promotion.'' 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.

Adherence Potential and Patient Preference in Prescription Drug Promotion

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality.

Through the evaluation of advertising features, we assess how elements such as graphics, format, and the characteristics of the disease and product impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience. Our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response