a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Study 1 Pretest					
Study 1 Pretest Screener Completes	630	1	630	.03 (2 minutes)	18.9
Study 1 Pretest Questionnaire Completes	126	1	126	.30 (18 minutes)	38
Study 2 Pretest					
Study 2 Pretest Screener Completes	420	1	420	.03 (2 minutes)	12.6
Study 2 Pretest Questionnaire Completes	126	1	126	.30 (18 minutes)	38
Study 1 Main Study					
Study 1 Main Study Screener Completes	3,240	1	3,240	.03 (2 minutes)	97.2
Study 1 Main Study Questionnaire Completes	648	1	648	.30 (18 minutes)	194
Study 2 Main Study					
Study 2 Main Study Screener Completes	2,160	1	2,160	.03 (2 minutes)	64.8
Study 2 Main Study Questionnaire Completes	648	1	648	.30 (18 minutes)	194
Total					657.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60.''

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. LaTour, C. and M. Smith, ''A Study of Expert Endorsement of OTC Pharmaceutical Products,'' *Journal of Pharmaceutical Marketing & Management,* Vol. 1, Issue 2, pp. 117–128, 1986.
2. Bhutada, N.S. and B.L. Rollins, ''Disease-Specific Direct-to-Consumer Advertising of Pharmaceuticals: An Examination of Endorser Type and Gender Effects on Consumers' Attitudes and Behaviors,'' *Research in Social and Administrative Pharmacy,* Vol. 11, Issue 6, pp. 891–900, 2015.
3. *Pharmaceutical Research and Manufacturers of America (PhRMA), ''PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines,'' *Pharmaceutical Research and Manufacturers of America,* Washington, DC, *https://www.phrma.org,* revised October 2018, available at *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Guiding_Principles_2018.pdf* (accessed May 18, 2022).
4. *Schouten, A.P., L. Janssen, and M. Verspaget, ''Celebrity vs. Influencer Endorsements in Advertising: The Role of Identification, Credibility, and Product-Endorser Fit,'' *International Journal of Advertising,* Vol. 39, Issue 2, pp. 258–281, 2020, *https://doi.org/10.1080/02650487.2019.1634898.*
5. *Bulik, B.S., ''Merck Adds Real Patient to 'TRU' Keytruda TV Ad,'' Fierce Pharma, September 27, 2017, available at *https://www.fiercepharma.com/marketing/new-merck-tv-ad-for-keytruda-continues-tru-theme-but-now-features-real-patient* (accessed May 18, 2022).

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08965 Filed 4–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3208]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

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 May 30, 2023.

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 0910–0284. 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.

Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

OMB Control Number 0910–0284—Extension

This information collection supports statutory and regulatory requirements governing reporting associated with certain animal drug products. With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4).

In 2020, FDA amended § 514.80 (21 CFR 514.80) to require electronic submission of certain postmarketing safety reports for approved new animal drugs and to provide a procedure for requesting a temporary waiver of the requirement. We, therefore, retain use of certain paper-based forms. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA. Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) on Form FDA 1932.

The information collection includes electronic submission of adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) using Form FDA 1932. The information collection also includes submissions under § 514.80(d)(2), by an applicant or nonapplicant requesting, in writing, a temporary waiver of the electronic submission requirements. The initial request may be by telephone or email to the Center for Veterinary Medicine's Division of Pharmacovigilance and Surveillance, with prompt written followup submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

Description of Respondents: Respondents to this collection of information are applicants and nonapplicants as defined in 21 CFR 514.3. Respondents include individuals and the private sector (for-profit businesses).

In the **Federal Register** of December 22, 2022 (87 FR 78694) FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received it was not responsive to any of the four information collection topics solicited in our notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated feed reports, 510.301(a) and (b).	N/A	8	1	8	0.25 (15 minutes)	2
Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3) , and (4)(iv)(A) and (C).	1932	85	1,249	98,639	1	98,639
Voluntary reporting FDA Form 1932a for the public.	1932a	106	1	106	1	106
514.80(b)(4) Periodic Drug Experience Reports.	2301	79	20	1,582	16	25,312
514.80(b)(5)(i) Special Drug Experience Reports.	2301	78	215	16,790	2	33,580
514.80(b)(5)(ii) Advertisement and Promotional labeling.	2301	38	192	7,282	2	14,564
514.80(b)(5)(iii) Distributor's Statements.	2301	22	2	36	2	72
514.80(d)(2)	N/A	1	1	1	1	1
Total						172,276

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping, 510.301 [2]	8	1	8	4	32

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e) [3]	79	1,575.14	124,436	14	1,742,104
Total	.....	.....	.....	.....	1,742,136

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.
[3] This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

Upon review of the information collection, we have adjusted our estimated burden to reflect an overall increase of 136,029.75 hours and 1,677,019 responses/records, annually.

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08999 Filed 4–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0341]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Federal-State Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 30, 2023.

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 0910–0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Federal-State Food Regulatory Program Standards

OMB Control Number 0910–0760—Revision

This information collection supports the FDA's Animal Food (formerly Feed) Regulatory Program Standards (AFRPS) and Egg Regulatory Program Standards (ERPS). In the United States, Federal and State government agencies ensure the safety of human and animal food. FDA is responsible for ensuring that all human and animal food moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure human and animal food produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of human and animal food facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect human and animal food.

The FDA Food Safety Modernization Act calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of human and animal food safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal agencies to ensure credibility of human and animal food programs within the IFSS. The AFRPS and ERPS provide a uniform and consistent approach to animal food and egg regulation in the United States. Implementation is voluntary.

The AFRPS and ERPS are the frameworks that each State should use to design, manage, and improve its animal food or egg regulatory program. Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a state program voluntarily agrees to implement the standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard. We invite you to visit our website (*https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/national-integrated-food-safety-system-ifss-programs-and-initiatives/regulatory-program-standards#:~:text=Regulatory%20program%20standards%20establish%20a,regulating%20human%20and%20animal%20food*) for more information and to access the program standards.

Both the AFRPS and ERPS packages include forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. States submit the information collected annually via email to the appropriate FDA program manager. Records and other documents specified in the AFRPS and ERPS must be maintained in good order by the state program and must be available to verify the implementation of each standard.

As set forth in the AFRPS and ERPS, the state program is expected to review and update its improvement plan on an annual basis. The state program completes an evaluation of its