These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson(s) of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements and the number of submissions received by FDA under the regulations over the past 3 years.

In the **Federal Register** of April 25, 2017 (82 FR 19052), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(3) (Reports) and (c)(4) (Approval); Form FDA 2914 (Membership Summary)	69	1	69	1	69
361.1(c)(3) (Reports); Form FDA 2915 (Study Summary)	35	14	490	3.5	1,715
361.1(c)(8) (Adverse Events)	10	1	10	*0.5	5
Total			569		1,789

[1] There are no capital or operating and maintenance costs associated with the information collection.
* 30 minutes.

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
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	14	490	*0.75	368
Total			766		3,128

[1] There are no capital or operating and maintenance costs associated with the information collection.
* 45 minutes.

Dated: July 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15000 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2428]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug Adverse Event Reporting and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 FDA's existing reporting and recordkeeping requirements for animal drug adverse events and product/manufacturing defects.

DATES: Submit either electronic or written comments on the collection of information by September 18, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2017–N–2428 for ''Animal Drug Adverse Event Reporting and Recordkeeping.'' Received comments, those filed in a timely manner (see **DATES**), 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.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. 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.

Animal Drug Adverse Event Reporting and Recordkeeping—21 U.S.C. 360b(l), 21 CFR 510.301 and 514.80 OMB Control Number 0910–0284—Extension

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 (the FD&C 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). Sections 571(e)(3) and 512(e)(2) of the FD&C Act (21 U.S.C. 360ccc(e)(3) and 360b(e)(2)) require that applicants with conditionally approved new animal drug applications (CNADAs) maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l). Finally, section 512(m)(5) of the FD&C Act requires an applicant for a license to manufacture animal feeds bearing or containing new animal drugs to maintain adequate records and make reports ''as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine'' whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) or a license to manufacture animal feeds bearing or containing new animal drugs under section 512(m)(4).

Section 514.80 of our regulations (21 CFR 514.80) sets forth the recordkeeping and reporting requirements for applicants and nonapplicants of approved NADAs and ANADAs. Section 510.301 of our regulations (21 CFR 510.301) sets forth the recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities.

Recordkeeping and Reporting Requirements for Applicants of Approved NADAs and ANADAs

Section 514.80 requires applicants 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 are required to submit adverse event reports and product defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) on Form FDA 1932. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the general public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 2301 is used by applicants to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug. We have made minor editorial revisions to Form FDA 1932a, to clarify how to report adverse drug events associated with compounded products using that form. Submitters are already reporting adverse drug events associated with compounded products on Form FDA 1932a. The clarifications include: The addition of a new question, ''Is this a compounded product''; the addition of a new field to allow the submitter to provide product strength, ''Strength of Active Ingredient(s)''; modifying the title of the existing field requesting the name of manufacturer, so that it reads, ''Name of Manufacturer or Compounding Pharmacy/Compounder of Suspected Product''; and a request for contact information for the manufacturer or compounder. We estimate that the revisions will not change the average amount of time necessary to complete the form.

Recordkeeping and Reporting Requirements for Applicants of CNADAs

As noted, sections 571(e)(3) and 512(e)(2) of the FD&C Act require that applicants for CNADAs maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l) of the FD&C Act. Moreover, section 512(l) requires submission of such information as required ''by general regulation, or by order . . .'' Conditional approval letters explicitly establish an order requiring the submission of postmarketing information in accordance with the requirements of § 514.80. Applicants submit adverse event reports and product defect reports on Form FDA 1932.

Recordkeeping and Reporting Requirements for Licensed Medicated Feed Manufacturing Facilities

Section 510.301 requires a licensed medicated feed manufacturer to keep records of and report to us information concerning experience with animal feeds bearing or containing approved new animal drugs. Under § 510.301(a), a licensed medicated feed manufacturer must immediately report to us information concerning any mixup in the new animal drug or its labeling; any bacterial or significant chemical, physical, or other change or deterioration in a drug; and any failure of one or more distributed batches of a drug to meet the specifications established for it. Under § 510.301(b), a licensed medicated feed manufacturer must report to us within 15 working days of receipt of information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof, and any unusual failure of the new animal drug to exhibit its expected pharmacological activity. OMB initially approved the information collection provisions of § 510.301 under control number 0910–0012. That approval was subsequently consolidated into this collection in 2004. We reviewed the records and reports required by § 510.301 to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) of the FD&C Act, or grounds for revoking a license to manufacture medicated feed under section 512(m)(4).

Since the consolidation of the 0910–0012 collection into this collection in 2004, we have included the estimated number of medicated feed adverse event reports as part of our estimate of the number of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates we have added a row to table 1, on which we separately report our estimates of medicated feed reports.

The continuous monitoring of approved NADAs, ANADAs, CNADAs, and animal feeds bearing or containing new animal drugs affords the primary means by which we obtain information regarding potential problems with the safety and efficacy of marketed approved new animal drugs, as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to us may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

Description of respondents: Respondents to this collection of information are animal drug manufacturers with approved NADAs, ANADAs, or CNADAs, as well as licensed commercial feed mills and licensed mixer-feeders.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form	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	5	1	5	.25 (15 minutes) ...	1.25
Mandatory adverse event reporting, 21 U.S.C. 360b(l); § 514.80(b)(1); (b)(2)(i) and (ii); (b)(3); and (b)(4)(iv)(A).	1932	22	81	1,782	1	1,782
Voluntary adverse event reporting by veterinarians and the general public.	1932a	197	1	197	1	197
Periodic drug experience reports, § 514.80(b)(4).	2301	200	8.11	1,622	16	25,952

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Special drug experience reports, § 514.80(b)(5)(i).	2301	200	0.57	114	2	228
Submission of advertisements and promotional labeling, § 514.80(b)(5)(ii).	2301	200	20.12	4,024	2	8,048
Submission of distributor statements, § 514.80(b)(5)(iii).	2301	190	0.1	19	2	38
Total						36,246.25

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

We base our reporting estimates on our experience with adverse event reporting for approved new animal drugs and the number of reports received in the previous 3 years.

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, § 510.301 [2]	5	1	5	4	20
Recordkeeping, 21 U.S.C. 360b(l) and § 514.80(e) [3]	646.70	7.19	4,649.8	14	65,097
Total					65,117

[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 CNADAs under § 514.80(e).

We base our recordkeeping estimates on our experience with adverse event reporting for approved new animal drugs and the number of reports received in the previous 3 years. Since the consolidation of the 0910–0012 collection into this collection in 2004, we have included the estimated recordkeeping burden for medicated feed adverse event reports as part of our estimate of the recordkeeping burden of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates we have added a row to table 2, on which we separately report our recordkeeping estimate for medicated feed adverse event reports (20 hours).

The burden of this collection has changed. Due to the addition of a new row to table 1 and a new row to table 2, there was a slight increase in the estimated number of reports submitted to FDA under total annual responses (by 7.8 responses). The overall decrease in burden hours (by 1.75 hours) is due to the normal variation in the submission of reports to FDA.

We continually strive to improve our systems for collecting and analyzing drug experience reports and adverse event reports. To that end, we have developed an electronic submission system by which Form FDA 2301 may be submitted to the Agency. For Form FDA 1932a, we have a fillable electronic form available online, which can be submitted by email to FDA Center for Veterinary Medicine. We specifically invite comment from respondents on the utility of these reporting forms. Electronic adverse event reporting for approved new animal drugs (including mandatory reporting under § 514.80(b) and voluntary reporting) has been approved under OMB control number 0910–0645. Reporting and recordkeeping associated with the index of legally marketed unapproved new animal drugs for minor species (21 CFR part 516) is approved under OMB control number 0910–0620.

Dated: July 11, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–14993 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0920]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey, as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 Health and Diet Survey as used by FDA to gauge and to track consumer attitudes, awareness, knowledge, and behavior