

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.

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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

regarding various topics related to health, nutrition, physical activity, and product labeling.

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-2014-N-0920 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey, as Used by the Food and Drug Administration." 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.

- **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. Mizrahi, 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.

Health and Diet Survey as Used by the Food and Drug Administration OMB Control Number 0910-0545—Extension

We are seeking to renew OMB approval of the Health and Diet Survey, which is a voluntary consumer survey intended to gauge and to track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. OMB approved this collection as a generic collection on December 5, 2014. The authority for FDA to collect the information derives from FDA's Commissioner of Food and Drugs authority provided in section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

We will use the Health and Diet Survey findings to test and refine our ideas, but will generally conduct further

research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

This survey has been repeated approximately every 3 to 5 years over the course of the past 3 decades for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified

in each iteration in response to emerging and current events or issues. In the next 3 years, we plan to field this survey two to three times. We will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy diets and lifestyles. The information will also help FDA evaluate and track consumer awareness and behavior as outcome

measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 States and the District of Columbia. Participation will be voluntary.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	100	1	100	0.08 (5 minutes)	8
Cognitive interview	18	1	18	1	18
Pretest screener	2,000	1	2,000	0.033 (2 minutes)	66
Pretest	200	1	200	0.25 (15 minutes)	50
Survey screener	40,000	1	40,000	0.033 (2 minutes)	1,320
Survey	4,000	1	4,000	0.25 (15 minutes)	1,000
Total					2,462

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

We base our estimate of the number of respondents and the average burden per response on our experience with previous Health and Diet Surveys and we estimate that the burden for this information collection has increased by 580 hours (from 1,882 to 2,462 hours) since the last OMB approval. The increase is due to an expected increase in the number of participants completing the survey screener (from 30,000 to 40,000 participants) and number of participants taking the survey (from 3,000 to 4,000). We will use a cognitive interview screener with 100 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.08 hours) to complete the cognitive interview screener, for a total of 8 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take a participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the Health and Diet Survey, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. We will use a pretest screener with 2,000 individuals; we estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the pretest screener, for a total of 66 hours. The pretest will be conducted with 200 participants; we estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 50 hours. We will use a survey screener to select an eligible adult

respondent in each household reached by landline telephone numbers to participate in the survey. A total of 40,000 individuals in the 50 states and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 2 minutes (0.033 hours) to complete the screening, for a total of 1,320 hours. We estimate that 4,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 1,000 hours. Thus, the total estimated burden is 2,462 hours.

We are requesting this burden for unplanned surveys so as not to restrict our ability to gather information on consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. This ability will help the Agency identify and respond to emerging issues in a more timely manner.

Dated: July 11, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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: Fax written comments on the collection of information by August 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0154. Also include the FDA docket number found in brackets in the heading of this document.