

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-D-2300 for “Evaluating Drug Effects on the Ability to Operate a Motor Vehicle.” 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.

- **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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Naomi Lowy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4204, Silver Spring, MD 20993-0002, 301-796-0692.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Evaluating Drug Effects on the Ability to Operate a Motor Vehicle.” The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle.

Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities that can be adversely affected by therapeutic drugs. Reducing the incidence of MVAs that occur because of drug-impaired driving is a public health priority.

Drugs that impair driving ability may also impair an individual’s ability to judge the extent of his or her own impairment. This increases the need for objective evaluation of the presence and degree of driving impairment, with risk mitigation strategies based on that information. This guidance recommends a systematic effort to identify drugs for which evaluation of effects on driving abilities may be needed and the types of studies that such an evaluation entails.

This guidance finalizes the draft guidance issued on January 16, 2015, (80 FR 2432) of the same name. Changes made to the guidance took into consideration comments received. In addition to editorial changes made primarily for clarification, the guidance

provides multiple areas of clarification throughout the document.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on evaluating drug effects on the ability to operate a motor vehicle. 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. This guidance is not subject to Executive Order 12866.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 3, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017-24367 Filed 11-8-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0920]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 December 11, 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0545. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

**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.

In the **Federal Register** of July 18, 2017 (82 FR 32832), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener .....	100	1	100	.08 ..... (5 minutes) .....	8
Cognitive interview .....	18	1	18	1 .....	18
Pretest screener .....	2,000	1	2,000	.033 (2 minutes) .....	66
Pretest .....	200	1	200	.25 (15 minutes) .....	50
Survey screener .....	40,000	1	40,000	.033 (2 minutes) .....	1,320
Survey .....	4,000	1	4,000	.25 (15 minutes) .....	1,000
<b>Total .....</b>					<b>2,462</b>

<sup>1</sup> 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: November 6, 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-1027]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Recall Regulations**

**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 December 11, 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 0910-0188. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601

Landsdown St., North Bethesda, MD 20852, 301-796-7726, *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.

**Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280, OMB Control Number 0910-0188—Extension**

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the

recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for FDA's written concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination, nutritional inadequacy, or is otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

In the **Federal Register** of June 15, 2017 (82 FR 27509), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment that was unrelated to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
107.230; Elements of an infant formula recall .....	2	1	2	4,450	8,900
107.240; Notification requirements .....	2	1	2	1,482	2,964
107.250; Termination of an infant formula recall .....	2	1	2	120	240
107.260; Revision of an infant formula recall <sup>2</sup> .....	1	1	1	625	625