one comment that was not responsive to the comment request on the information collection provision.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
516.20	15	5	75	16	1,200
516.26	3	1	3	2	6
516.27	1	1	1	1	1
516.29	2	1	2	1	2
516.30	15	5	75	2	150
516.36	1	1	1	3	3
Total					1,362

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

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current investigational new animal drug (INAD)/new animal drug application (NADA) reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community.

Dated: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24273 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0373]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

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: Fax written comments on the collection of information by October 28, 2010.

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 0910–0541. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (OMB Control Number 0910–0541)—Extension

As an integral part of its decisionmaking process, FDA is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions and GRAS petition requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in part 25 (21 CFR part 25) to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required Environmental Assessment (EA) and abbreviated EA formats from the amended regulations. Instead, FDA has provided guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to FDA's Center for Food Safety and Applied Nutrition (CFSAN). The guidance document entitled "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

The guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following

questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) what must a claim of categorical exclusion include by regulation? (3) what is an EA? (4) when is an EA required by regulation and what format should be used? (5) what are extraordinary circumstances? and (6) what suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. FDA is requesting the extension of OMB approval for the information collection provisions in the guidance. The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of July 21, 2010 (75 FR 42446), FDA published a 60-day notice requesting public comment on the proposed collection of information. In response, the agency received one comment that was not responsive to the comment request on the information collection provisions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.32(i)	34	1	34	1	34
25.32(o)	1	1	1	1	1
25.32(q)	2	1	2	1	2
Total					37

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

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24272 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Testing Successful Health Communications Surrounding Aging-Related Issues From the National Institute on Aging (NIA)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Aging, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Testing successful health communications surrounding aging-related issues from the National Institute on Aging (NIA). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will support NIA's mission "to communicate information about aging and advances in research on aging to the scientific community, health care providers, and the public." The primary objectives of this study are to:

- Assess audiences' trusted/preferred sources for information, knowledge, attitudes, behaviors, and other characteristics for the planning/development of health messages and communications strategies;
- Pre-test health messages and outreach strategies while they are in developmental form to assess audience response, including their likes and dislikes.

NIA's Office of Communications and Public liaison will collect this information through formative qualitative research with its key audiences—older people, caregivers, and health professionals. Methods will include focus groups, individual interviews, self-administered questionnaires, and website surveys. The information will be used to (1) Develop and revise health information resources and outreach strategies to maximize their effectiveness; (2) determine new topic areas to explore for future NIA publications; and (3) identify new ways to support the health information needs of older adults and people who serve older adults. NIA is requesting a generic clearance for a range of research data collection procedures to ensure that they successfully develop and disseminate effective health communications on aging-related issues. *Frequency of Response:* On occasion. *Affected Public:* Older people, caregivers, and health professionals (physicians and non-physicians). *Type of Respondents:* Older