deemed appropriate) discussing the health effects of these ingredients.

HHS has delegated responsibility for implementing the required information collection to CDC's Office on Smoking and Health. Respondents are not required to submit specific forms; however, they are required to meet reporting guidelines and to submit the ingredient report by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies that are required to report ingredients added to other consumer products. Typically, respondents submit a summary report to CDC with the ingredient information for multiple products, or a statement that there are no changes to their previously submitted ingredient report. Respondents may submit the required information to CDC through a designated representative. The information collection is subject to strict confidentiality provisions.

Ingredient reports for new SLT products are due at the time of first importation. Thereafter, ingredient reports are due annually on March 31. Information is submitted to OSH by mailing a written report on the respondent's letterhead, by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Upon receipt and verification of the annual nicotine and ingredient report, OSH issues a Certificate of Compliance to the respondent.

There are no changes to information collection procedures or the estimated burden per response. There is an increase in total estimated burden due to an increase in the estimated number of respondents, from 11 to 13. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Smokeless Tobacco Manufacturers, Packagers, and Importers.	SLT Nicotine and Ingredient and Report.	13	1	1,713	22,269

Kimberly S. Lane,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–4950 Filed 2–29–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Objective Work Plan (OWP), Objective Progress Report (OPR) and Project Abstract.

OMB No.: 0980–0204.

Description: Content changes are being proposed for the OPR and OWP ONLY. The information in the OPR is collected on a quarterly basis to monitor the performance of grantees and better gauge grantee progress. The standardized format allows ANA to report results across all its program areas and flag grantees that may need additional training and/or technical assistance to successfully implement their projects. The following are proposed changes within specific sections of the OPR form:

Objective Work Plan Update Section: ANA has added fields for 1st through 4th Quarter (Q1,Q2,Q3,Q4) to report the results for activities within each Project Objective. The grantee may continue to add to this form each quarter (rather than to a new form), reflecting cumulative results throughout the project period instead of a single quarter.

Financial Section: ANA has added 2 questions to: (1) Provide details on any income generated as a result of ANA project activities; (2) Provide details on any changes made to the budget during the reporting period.

Native American Youth and Elder Opportunities Section: ANA has added a question to: (1) Request details on any intergenerational activities between grandparents and their grandchildren. Finally, ANA has added a new section (last section) to the form titled: PROJECT SUSTAINABILITY, to: (1) Request details on the grantee's intention to continue the project benefits and/or services after ANA's funding period for the project has ended.

End of Changes to the OPR

The OWP: The information collected through the OWP is needed to properly administer and monitor the Administration for Native Americans (ANA) programs. The OWP assists applicants in describing their projects' objectives and activities, and also assists independent panel reviewers, ANA staff and the ANA Commissioner during review and funding decision process.

Changes Specific Sections of the OWP

Problem Statement: ANA added a field for applicants to include the problem statement they identified in their grant application.

Position Performing the Activity: On the previous OWP, ANA requested applicants to identify the position responsible for each activity. ANA has changed this title to ''position performing the activity'' and applicants are asked to identify the lead person in one column and other support persons in the second column.

End of Changes to the OWP

Project Abstract: The Project Abstract form is no longer managed by ANA.

Respondents: Tribal Government, Native Non-profit Organizations, Tribal Colleges & Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP	500	1	3	1,500
OPR	275	4	1	1,100

Estimated Total Annual Burden Hours: 2,850.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. Fax: 202–395–7285. Email: *OIRA_SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–4973 Filed 2–29–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0766]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of ''Health Care Providers' Responses to Medical Device Labeling''

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 April 2, 2012.

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–NEW and title ''Survey of 'Health Care Providers' Responses to Medical Device Labeling' ''). Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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.

Survey of ''Health Care Providers' Responses to Medical Device Labeling''—21 CFR Part 801 (OMB Control Number 0910–NEW)

The purpose of this study is to determine the most effective device labeling format and inform an FDA's regulatory approach on standardized device labeling. Building upon the research methodology and success of the approach FDA used to evaluate drug labeling, we propose to ask health care providers (HCPs) to evaluate the quality of labeling (*e.g.* instructions for use, directions) for a medical device and to report the degree to which they could follow those instructions, how useful the information is, and how well organized the information is. This work will allow FDA to assess whether HCPs find the format and content of device labeling clear, understandable, useful, and user-friendly. Findings will provide evidence to inform FDA's regulatory approach to standardizing medical device labeling across the United States.

In the **Federal Register** of November 1, 2011 (76 FR 67459), FDA published a 60-day notice requesting public comment on the proposed collection of information.

Two comments were received, however only one was related to the Paperwork Reduction Act of 1995. In response to the comments submitted by Advamed, FDA responses are as follows:

(Comment 1) Comment 1 questioned whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

(Response) The survey is designed to elicit responses on the formatting, content, and design of the template and not on the specific medical device chosen. This is stated at the beginning of the survey. FDA relies upon knowledgeable researchers to develop appropriate survey tools, and the research methodology to test content, format, and design of labeling is based on their expertise. Drugs instructions are written for all users, including health care providers and patients. The device labeling is written for all users, including health care providers and patients. We agree that industry could provide recommended contents and formats of labeling and encourage industry to do so. This survey is designed for the health care provider and their feedback.

(Comment 2) Comment 2 questioned the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

(Response) The survey is designed to elicit responses on the formatting, content, and design of the template and not on the specific medical device chosen. The terms used in the templates such as ''warnings'', ''contraindications'', and ''brand name'' are commonly used terms in labeling for all devices. We are addressing what should be in a shortened version of labeling that will allow the user to operate it safely. The survey was designed by researchers with extensive knowledge in the area of testing labeling. It is anticipated that different health care practitioners will provide different answers based on their experiences; this is why we chose to ask various types of health care practitioners. The objective of the survey is to improve device labeling; it would not be possible to do a survey with a fictitious device that has no intended use as per the suggestion. All devices need to have intended use.

(Comment 3) Comment 3 questioned ways to enhance the quality, utility, and clarity of the information to be collected.

(Response) We did not choose biomedical engineers as part of this survey because we wanted the people who interact with the pump in the presence of patients. The suggestion to add a question about whether a health care professional ever uses or reads device labeling and how to improve access to current device labeling was done in a previous study with focus groups. We developed the template survey based on the responses we