recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling, FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) require such labeling, and the information collection associated with these regulations is approved by OMB under OMB Control Number 0910–0572.

(2) Section VI.B of the guidance requests that the format of cardiovascular outcome claim prior approval supplements submitted to FDA under the guidance should include the following information:

1. A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150

2. Applicable FDA forms (e.g., 356h, 3397)

3. Detailed Table of Contents

4. Revised labeling:

a. Include draft revised labeling conforming to the requirements in §§ 201.56 and 201.57

b. Include marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission

FDA estimates that approximately 70 cardiovascular outcome claim supplements will be submitted annually from approximately 30 different companies, and that each supplement will take approximately 4 hours to prepare and submit. The guidance also recommends that other labeling changes (e.g., the addition of adverse event data) should be minimized and provided in separate supplements, and that the revision of labeling to conform to §§ 201.56 and 201.57 may require substantial revision to the ADVERSE REACTIONS or other labeling sections.

(3) Section VI.C of the guidance states that applicants are encouraged to include the following statement in promotional materials for the drug.

"[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals."

The inclusion of this statement in the promotional materials for the drug would be exempt from OMB review based on 5 CFR 1320.3(c)(2), which states that "The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included * * *" within the definition of "collection of information."

FDA requests public comments on the information collection provisions described previously and set forth in the following table:

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

ESTIMATED ANNUAL REPORTING BURDEN

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours Per Response	Total Hours
Submission to Docket Number FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	30	2.33	70	4	280
Total					290

Dated: March 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6173 Filed 3–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0122]

Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups About Drug Products, as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on focus groups about drug products used by FDA to gauge informally public opinion, on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to, direct-to-consumer (DTC) prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter (OTC) drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

DATES: Submit written or electronic comments on the collection of information by May 21, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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 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.

Focus Groups About Drug Products, as Used by the Food and Drug Administration

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies,
- To better understand people's attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine its ideas and to help develop messages and other communications, 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.

FDA's Center for Drug Evaluation and Research, Office of the Commissioner, and any other centers or offices conducting focus groups about regulated drug products may need to conduct focus groups on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to, DTC prescription drug promotion, physician labeling of prescription drugs, Medication Guides, OTC drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	No. of Responses per Respondent	Total Annual Responses (Hours)	Hours per Response	Total Hours
1,440	1	1,440	1.75	2,520

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

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: March 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–6172 Filed 3–19–10; 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: ANA Project Impact Assessment Survey.

OMB No.: New Collection.

Description: The information collected by the Project Impact Assessment Survey is needed for two main reasons: (1) To collect crucial information required to report on the Administration for Native Americans' (ANA) established Government Performance and Results Act (GPRA) measures, and (2) to properly abide by ANA's congressionally-mandated statute (42 United States Code 2991 *et seq.*) found within the Native American Programs Act of 1974, as amended, which states that ANA will evaluate projects assisted through ANA grant dollars "including evaluations that describe and measure the impact of such projects, their effectiveness in achieving stated goals, their impact on related programs, and their structure and mechanisms for delivery of services." The information collected with this survey will fulfill ANA's statutory requirement and will also serve as an important planning and performance tool for ANA.

Respondents: Tribal Governments, Native American nonprofit organizations, and Tribal Colleges and Universities.