specific topic and as a qualitative research tool have two major purposes:

- To obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns, and
- To assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences.

FDA will use these methods 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, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale 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]

Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
19,822	1	19,822	0.24	4,757

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

Annually, FDA projects about 45 communication studies using the variety of test methods listed previously in this document. FDA is requesting this burden 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: *February 1, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2663 Filed 2–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0493]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded

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 March 10, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—New and title "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded." Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded—(OMB Control Number 0910—New)

In the **Federal Register** of January 23, 2002 (67 FR 3060), we established regulations in § 330.14 (21 CFR 330.14) providing additional criteria and procedures for classifying over-the-counter (OTC) drugs as generally recognized as safe and effective and not misbranded (2002 time and extent application (TEA) final rule). The regulations in § 330.14 state that OTC drug products introduced into the U.S. market after the OTC drug review began and OTC drug products without any marketing experience in the United States can be evaluated under the monograph process if the conditions (*e.g.,* active ingredients) meet certain "time and extent" criteria outlined in § 330.14(b). The regulations allow a TEA to be submitted to us by any party for our consideration to include new conditions in the OTC drug monograph system. TEAs must provide evidence described in § 330.14(c) demonstrating that the condition is eligible for inclusion in the monograph system. (Section 330.14(d) specifies the number of copies and address for submission of a TEA.) If a condition is found eligible, any interested parties can submit safety and effectiveness information as explained in § 330.14(f). Safety and effectiveness data include not only the data and information listed in 21 CFR 330.10(a)(2) (§ 330.14(f)(1)), but also a listing of all serious adverse drug experiences that may have occurred (§ 330.14(f)(2)) as well as an official or proposed compendial monograph (§ 330.14(i)).

In the **Federal Register** of October 8, 2010 (75 FR 62404), we published a 60-day notice requesting public comment on the proposed collection of information. In that notice, we stated that we considered our estimate, in the 2002 TEA final rule, of 480 hours to prepare a TEA and 800 hours to prepare and submit safety and effectiveness data to continue to be valid (75 FR 62404 at 62405). In the same document, we stated that, based on the number of submissions we had received in the 8 years following publication of the TEA final rule, we expected to receive an

average of two TEAs and two submissions of safety and effectiveness data each year. Therefore, we estimated the total annual reporting burden to be 2,560 hours. This number included 960 hours for preparing TEAs (two TEAs per year times 480 hours per TEA) and 1,600 hours (two submissions of safety and effectiveness data times 800 hours per submission).

We received a submission from a manufacturer that filed two TEAs stating that our estimates in the 60-day notice were too low. The submission noted that the time spent on "gathering, compiling, evaluating and preparing" the TEA and safety and effectiveness submissions was "significantly greater" than what FDA had estimated in the 2002 TEA final rule and the more recent 60-day notice. The submission estimates that approximately 1,526 hours are required to prepare a TEA and approximately 2,348 hours to prepare a safety and effectiveness submission.

Because the information provided in the submission is based on actual experience by a TEA applicant, we agree with the submission and are adjusting our estimates in this document accordingly. We continue to estimate that we will receive two TEAs and two safety and effectiveness submissions each year. We now estimate that it will take approximately 1,525 hours to prepare a TEA and 2,350 hours to prepare a comprehensive safety and effectiveness submission.

The submission included, as part of the estimated burden of safety and effectiveness data submission, an estimated burden to submit environmental data. We agree with the submission and are including the environmental data in our estimated burden of safety and effectiveness data submission. In February 2010, we published a call-for-data to request data on the environmental impact of amending OTC drug monographs to include any of 13 active ingredients that were found eligible for potential inclusion in an OTC monograph through the TEA process (75 FR 7606, February 22, 2010). In that document, we explain that a proposed rule that would add an ingredient to an OTC drug monograph would be subject to the National Environmental Policy Act of 1969 (NEPA) (see 21 CFR 25.1). In order to comply with NEPA, an environmental assessment of such an Agency action is required, unless we determine that a categorical exclusion is warranted (21 CFR 25.20(f)). Therefore, in this document, the estimated burden of collection for safety and effectiveness data submission includes the burden to collect environmental data to support the application of any categorical exclusion or to conduct an environmental assessment, if necessary.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
330.14(c) and (d) [2]	2	1	2	1,525	3,050
330.14(f) and (i) [3]	2	1	2	2,350	4,700
Total					7,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] TEA.
[3] Safety and effectiveness submission, including environmental data in accordance with 21 CFR 25.1.

Dated: February 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2692 Filed 2–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0594]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Focus Groups as Used by the Food and Drug Administration (All Food and Drug Administration Regulated Products)

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 March 10, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0497. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *e-mail: Jonnalynn.capezzuto@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.

Focus Groups as Used by the Food and Drug Administration (All FDA-Regulated Products)—(OMB Control Number 0910–0497)—Extension

FDA conducts focus group interviews on a variety of topics involving FDA-regulated products, including drugs, biologics, devices, food, tobacco, and veterinary medicine.

Focus groups provide an important role in gathering information because they allow for a more indepth understanding of consumers' 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 consumer information that is useful for developing variables and measures for quantitative studies,
- To better understand consumers' attitudes and emotions in response to topics and concepts, and