TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section/FDA form No.	Number of respondents [4]	Annual frequency per respondent	Total annual responses	Hours per response	Total hours
514.8(b)	154	2.84	437.36	35	15,308
514.8(c)(1)	154	.1	15.4	71	1,093
514.8(c)(2) and (c)(3)	154	.7	107.8	20	2,156
514.11	154	.2	30.8	1	31
558.5(i)	154	.01	1.54	5	8
514.1(b)(8) and 514.8(c)(1) [3]	154	.21	32.34	90	2,911
FDA Form 356V	154	5.1	785.4	5	3,927
Total					33,319

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Substantial Evidence—Because 21 CFR 514.4 only defines substantial evidence, it should not be viewed as creating additional collection burden.
[3] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.
[4] Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 154 annual respondents during the 5 fiscal years, from October 1, 2005, through September 30, 2010, on which these estimates were made. We use this estimate consistently throughout the table and calculate the "annual frequency per respondent" by dividing the total annual responses by the number of respondents.

Dated: February 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–2664 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–2011–N–0067]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Drug Product Communications, 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 a generic clearance to collect information to support communications used by FDA about drug products. This data collection will informally gauge public opinion on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug and biological 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 sales of medical products, and consumer and professional education.

DATES: Submit either electronic or written comments on the collection of information by April 11, 2011.

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.

Data to Support Drug Products Communications, as Used by the Food and Drug Administration (OMB Control Number 0910–New)

Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews. The methods to be used serve the narrowly defined need for direct and informal opinion on a

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