Respondents: 50 States and 9 Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands and Palau

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application to include program narrative	59	1	40	2360
Performance Progress Reports	59	2	10	1180
Year 1 Implementation Plan	59	1	30	1770
Performance Measure Reporting	59	1	10	590

Estimated Total Annual Burden Hours: 5900.

Additional Information:

The Year 1 Implementation Plan is only required to be completed and submitted in the first year of the project period. This is a one time submission and will not occur annually.

The potential awardees could include organizations and other entities awarded in year 3 of the project period in States that did not apply for funding in the first 2 years of the project period.

A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275. Interested persons are invited to submit comments regarding this request. Comments must be received within thirty days from the publication date of this Notice.

Comments about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503; FAX: (202) 395–7285; e-mail: *oira_submission@omb.eop.gov.*

Dated: May 25, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–13106 Filed 6–2–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0248]

Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

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, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

DATES: Submit either electronic or written comments on the collection of information by August 2, 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, including each proposed reinstatement of an existing 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.

Format and Content Requirements for OTC Drug Product Labeling (OMB Control Number 0910 0340)—Reinstatement

In the **Federal Register** of March 17, 1999 (64 FR 13254), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201) (the 1999 labeling final rule). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

The only burden to comply with the regulations in part 201 is a one-time burden for OTC sunscreen products and new OTC drug products introduced to the marketplace under new drug applications (NDAs) or abbreviated new drug applications (ANDAs). All OTC drug products except sunscreens and new OTC products marketed under NDAs or ANDAs are already required to be in compliance with these labeling regulations. On June 20, 2000 (65 FR 38191), we published a **Federal Register** document that required all OTC drug products marketed under the OTC monograph system except sunscreen products to comply with the regulations by May 16, 2005, or sooner (65 FR 38191 at 38193). Sunscreen products do not have to comply with the regulations until we lift the stay of the sunscreen final rule that was published in the **Federal Register** on May 21, 1999 (64 FR 27666) (the 1999 sunscreen final rule). In the **Federal Register** of December 31, 2001 (66 FR 67485), we stayed the 1999 sunscreen final rule indefinitely. In the **Federal Register** of September 3, 2004 (69 FR 53801), we delayed the § 201.66 implementation date for OTC sunscreen products indefinitely. Because the compliance date has passed for all OTC drug products except sunscreens and drug products introduced under new NDAs or ANDAs, we believe that the labeling burden associated with the 1999 labeling final rule applies only to these products. We do not anticipate receiving any requests for exemptions or deferrals under § 201.66(e) because we have only received one request in the past 8 years.

We estimate that there are 4,750 OTC sunscreen drug product stock keeping units (SKUs) that have not yet complied with the 1999 labeling final rule. All of these SKUs will need to implement the new labeling format by the implementation date included in the 1999 sunscreen final rule when it is published in the **Federal Register**. We estimate that these 4,750 SKUs are marketed by 400 manufacturers and that approximately 2 hours will be spent on each submission (see table 1 of this document). The number of hours per submission (response) is based on our estimate in the 1999 labeling final rule (64 FR 13254 at 13276). If an average of 2 hours is spent preparing, completing, and reviewing each of the estimated 4,750 sunscreen SKUs, the total number of hours dedicated to the labeling of sunscreen products would be 9,500 hours (4,750 SKUs times 2 hours/SKU) (see table 1 of this document).

Based on estimates provided by the Consumer Healthcare Products Association, we believe that approximately 500 new OTC drug product SKUs marketed under NDAs or ANDAs are introduced to the marketplace each year. We estimate that these SKUs are marketed by 300 manufacturers. We estimate that the preparation of labeling for new NDAs and ANDAs will require 5 hours to prepare, complete, and review new labeling prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 2,500 hours (see table 1 of this document).

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
201.66(c) and (d)[2]	400	11.88	4,750	2	9,500
201.66(c) and (d)[3]	300	1.67	500	5	2,500
Total					12,000

[1] FDA estimates that capital costs of 22 to 25 million dollars will result from preparing labeling content and format in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.
[2] Burden for manufacturers of sunscreen drug product.
[3] Burden for manufacturers of products marketed under new NDAs or ANDAs.

Dated: May 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13279 Filed 6–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality; Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the AHRQ Limited Competition: PROSPECT STUDIES—Building New Clinical Infrastructure for CE (R01) applications are to be reviewed