Dated: July 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16804 Filed 7–8–10; 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; Submission for Office of Management and Budget Review; 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 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 August 9, 2010.

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

Focus Groups About Drug Products, As Used By the Food and Drug Administration—(OMB Control Number 0910–New)

Focus groups provide an important role in gathering information because they allow for a more indepth 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, 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.

In the **Federal Register** of March 22, 2010, (75 FR 13548), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Number 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: July 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16769 Filed 7–8–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0306]

Agency Information Collection Activities; Proposed Collection; Comment Request; "The Dairy Practitioner's Role in Residue Avoidance Survey"

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 FDA's "The Dairy Practitioner's Role in Residue Avoidance Survey."

DATES: Submit either electronic or written comments on the collection of information by September 7, 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: Denver Presley, Jr., Office of information Management, Food and Drug Administration, 350 Piccard Dr., P150–400B, 301–796–3793.

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.

"The Dairy Practitioner's Role in Residue Avoidance Survey" (OMB Control Number—0910–NEW)

The Food and Drug Administration (FDA), through its Center for Veterinary Medicine (CVM), regulates the manufacture and distribution of food additives and drugs that will be given to animals. FDA is responsible for investigating veterinary drug residue violations in meats and providing regulatory action when necessary. In connection with this mission, the CVM Office of Surveillance and Compliance (OSC) develops programs to promote veterinary drug residue awareness and avoidance in order to reduce the risk of drug residues in safeguarding the public health. Information will be collected to determine the current state of veterinary drug residue avoidance in the dairy industry.

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) and FDA are responsible for collecting data on tissue residues of animal drugs. Information from this survey will be analyzed and used to: (1) Identify the respondent's level of awareness of the veterinary drug residues in dairy beef; (2) assess the current level of participation in the existing residue avoidance programs i.e., the Food Animal Residue Avoidance Database and Dairy Beef Quality Assurance Program; (3) identify risk factors currently associated with drug residues in dairy tissues; and (4) identify the best way to disseminate drug residue avoidance information to dairy producers. Information from this study will be used to shape the Agency's efforts to develop educational materials and to identify ways in which the Agency can optimize resources in the area of drug residue avoidance. Further, the findings will be presented in a descriptive report and informational sheets will be disseminated to animal health officials, dairy producers, and veterinarians. Participation in this survey is voluntary. It is up to the individual dairy practitioner to determine if participation is desirable.

"The Dairy Practitioner's Role in Residue Avoidance Survey" will be comprised of a one time study that will employ a web-based self-administered survey instrument, followed by mailing of the same survey in a paper self-administered mode to increase coverage and response rate. The instrument will collect information on the respondent's knowledge of drug residues in dairy beef and experience with drug residues at their clients' dairy farms. The study will be disseminated via the American Association of Bovine Practitioners (AABP) e-mail list-serve. Mail and electronic correspondence promotional material will be disseminated throughout the process to increase response rates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Study	No. of respondents	Annual Frequency per response	Total Annual Responses	Hours per Response	Total Hours
Survey	2,890	1	2,890	.33	953.7
Total					

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

There will be 2,890 respondents for a one-time survey total of 2,890 annual responses. The hours per response is estimated to be .33 hours. Thus the total annual burden is estimated to be 953.7 hours. A 60 percent response rate is expected.

Dated: July 1, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16806 Filed 7–8–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0124]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

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 (the PRA).

DATES: Fax written comments on the collection of information by August 9, 2010.

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 "Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act." 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, *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.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Smokeless Tobacco Act (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires that manufacturers, packagers, importers, distributors, and retailers (in limited circumstances) of smokeless tobacco products include one of four specified health warning label statements on product packages and in advertisements.[1] The Smokeless Tobacco Act, as amended, also requires smokeless tobacco product manufacturers, importers, distributors, and certain retailers to submit a plan to FDA specifying the method to rotate, display, and distribute the specified health warning label statements required to appear in advertising and packaging. FDA is required to review each plan submitted and approve the plan if it provides for rotation, display, and distribution of warnings in compliance with the requirements of the Smokeless Tobacco Act. To the best of FDA's knowledge, all of the affected companies have previously submitted similar plans to the Federal Trade Commission (FTC), which had authority to implement the requirements of the Smokeless Tobacco Act prior to the Tobacco Control Act's amendments. However, because the requirements of the Smokeless Tobacco Act have been revised and because FDA now has authority to implement the Smokeless Tobacco Act, each affected company will be required to submit a new plan to FDA instead of FTC. The Tobacco Control Act's amendments to the Smokeless Tobacco Act are effective on June 22, 2010.

On August 7, 2007, FTC published a 30-day notice (72 FR 44138) announcing an opportunity for public comment and that the information collection would be sent to OMB for review. Based on FTC's previous experience with the submission of rotational plans and FDA's experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act), FDA estimates that there are 14 companies affected by this information collection. To account for the entry of new smokeless tobacco companies who may be affected by this information collection, FDA is estimating the total number of respondents to be 20.

When FTC originally implemented the rotational plan requirements in 1986, the Smokeless Tobacco Council, Inc., indicated that the six companies it represented would require 700–800 hours in total (133 hours each) to complete an initial rotational plan, involving multiple brands, multiple brand varieties, and multiple forms of both packaging and advertising. When FTC requested an extension of their PRA clearance in 2007, FTC decreased the estimate for submitting an initial plan from 143 hours to 60 hours, accounting for increased computerization and improvements in electronic communication over the subsequent 20 years since the Smokeless Tobacco Act was enacted. FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable. However, because the requirements of the new Smokeless Tobacco Act are unfamiliar to industry, FDA is increasing the time estimate for submitting initial plans to 100 hours.

In the **Federal Register** of March 16, 2010 (75 FR 12552), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on this information collection.

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

[1] The warnings themselves disclose information completely supplied by the Federal Government. As such, the disclosure does not constitute a "collection of information" as it is defined in the regulations implementing the PRA, nor, by extension, do the financial resources expended in relation to it constitute paperwork "burden." (*See* 5 CFR 1320.3(c)(2).)