under OMB control number 0910–0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 are under OMB control number 0910–0449; and the collections of information in 21 CFR 56.115 are approved under OMB control number 0910–0130.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06128 Filed 3–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Proposed Collection; 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 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 extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on submission of rotational plans for health warning label statements for smokeless tobacco products.

DATES: Submit either electronic or written comments on the collection of information by May 17, 2013.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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 extension 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.

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 0910–0671)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA.

This information collection—the submission to FDA of warning plans for smokeless tobacco products—is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

Based on the Federal Trade Commission's (FTC's) previous experience with the submission of warning 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 (21 U.S.C. 387s)), FDA estimates that there are 36 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is estimating the total number of respondents to be 100.

When the FTC requested an extension of their approved information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of rotational plans for health warning label statements	100	1	100	60	6,000	$1,200

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

FDA estimates a total of 100 respondents at 1 response each and 60 burden hours per response for a total of 6,000 burden hours (100 respondents × 1 response × 60 burden hours = 6,000 total burden hours). In addition, capital costs are based on all 100 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to be $1,200.

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06127 Filed 3–15–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0206]

Center for Drug Evaluation and Research Medical Policy Council; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on medical policy issues that may be considered by the CDER Medical Policy Council (Council) in FDA's Center for Drug Evaluation and Research (CDER). These comments will help the Agency identify and address medical policy issues that need clarification through guidance, notice and comment procedures, or other means.

DATES: Submit either electronic or written comments by July 16, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–301), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sandra J. Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6340, Silver Spring, MD 20993–0002, 301–796–1042, FAX: 301–847–3529, email: *cdermedicalpolicycouncil@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In January 2012, CDER established the Council to ensure better coordination of medical policy development and implementation within CDER and consistent, predictable communication of medical policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by CDER's Associate Director for Medical Policy, the Council provides a senior-level forum through which medical policy issues can be raised, considered, developed, and implemented. Council members include the following senior clinical leaders: The Center Director, the Deputy Center Director for Clinical Science, the Director of the Office of New Drugs, and the Director of the Office of Surveillance and Epidemiology. Experts from within CDER and other FDA offices provide expertise as needed for specific policy topics under consideration. By establishing this docket, FDA encourages the public to recommend specific topics for consideration by the Council. The Agency believes that this process will also ensure additional transparency in CDER's approach to medical policy development and implementation.

II. Range of Medical Policy Issues To Be Considered

FDA envisions a variety of topics that may be relevant for consideration by the Council. Specific topics could address issues related to the following: (1) Clinical evidence of effectiveness or safety, (2) clinical study/trial design, (3) professional and patient labeling, (4) prescription drug promotion, (5) human subjects protection, (6) bioresearch monitoring, (7) good clinical practice, (8) counter-terrorism drug development (such as in the application of the Animal Rule, 21 CFR 314.600), and (9) postmarketing surveillance. To be considered by the Council, a medical policy issue typically would meet one or more of the following criteria:

- A novel medical policy issue requiring senior management input;
- An issue on which CDER seems to have taken inconsistent positions;
- An existing medical policy position that should be reconsidered in light of scientific or regulatory advances;
- A complex safety management issue requiring senior management input;
- A medical policy that may be triggered by a specific product, but that will be applicable to other products; or
- Strategies for implementation of a new policy.

III. Establishment of a Docket and Request for Comments

FDA is requesting public suggestions, recommendations, and comments for topics (including scientific, clinical, regulatory, or other topics) on existing or novel medical policy issues that may warrant consideration by the Council. Comments should describe the following: (1) The medical policy issue recommended for discussion, (2) the rationale for doing so (e.g., clarifying previous advice or precedents, reconciling apparently differing perspectives within CDER or between CDER and regulated industry), (3) recommendations on how the medical policy issue could be addressed or implemented; and (4) existing policy documents (e.g., final guidance) relevant to the medical policy issue. Note that policy issues concerning any draft guidance should be submitted to the docket for that draft guidance.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the