ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form name & number (CFR reference)	Respondents	No. of respondents	No. of responses per respondent	Average burden per respondent (in hours)
Authorization Form 42 CFR 83.7	Person authorizing a party to submit a petition on his/her behalf.	20	1	3/60

Dated: July 13, 2010.

Carol Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–17685 Filed 7–19–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0367]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Request Regarding Menthol in Cigarettes

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 an information request regarding the use of menthol in cigarettes.

DATES: Submit either electronic or written comments on the collection of information by September 20, 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: 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: 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.

Information Request Regarding Menthol in Cigarettes—(OMB Control Number 0910–0662)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 917 of the Tobacco Control Act requires the Secretary of Health and Human Services (the Secretary) to establish a Tobacco Products Scientific Advisory Committee (TPSAC). Section 907(e) of the Tobacco Control Act requires the TPSAC to submit a report and recommendations to the Secretary on the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. To ensure a comprehensive review of this issue, the Center for Tobacco Products is requesting tobacco industry data and information to support the work of TPSAC. Under section 907(e) of the Tobacco Control Act, TPSAC must submit its report and recommendations to the Secretary within 1 year of its formation, or March 23, 2011.

In order to provide TPSAC with the information it needs to carry out its statutory obligation, FDA is requesting that tobacco companies submit information under section 904(b) of the Tobacco Control Act. OMB granted emergency processing and approved the information collection on May 12, 2010. In a letter dated May 26, 2010, FDA asked tobacco manufacturers to submit documents containing scientific, marketing, and health-related information pertaining to the use of menthol in cigarettes.

FDA has requested that tobacco manufacturers submit all documents and underlying scientific information relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on a specified set of topics. "Research activities" may include, but are not limited to, focus groups, surveys, experimental clinical studies, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices. Scientific and health-related information FDA has requested include

dose-response relationships for physiologic effects and chemosensory effects of mentholated tobacco smoke. FDA also requested information on the impact of menthol on the neurobiology of tobacco dependence and information on dose-related interactions between menthol and nicotine, including on the uptake and metabolism of nicotine and on various consumer perceptions of the product.

FDA has also requested tobacco companies to submit consumer research data and marketing information pertaining to menthol cigarettes. FDA requested consumer research data pertaining to use, cessation, and consumer perception of menthol cigarettes. FDA's request for documents and underlying scientific information related to marketing information includes data and information on marketing strategies for each brand or subbrand of menthol cigarettes, including strategies targeted to particular demographic groups, strategies aimed at tobacco-naïve consumers, and strategies aimed at recruitment of former tobacco users.

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

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs
Submission of Menthol Documents	116	1	116	140	16,240	$1,940

The capital costs associated with this collection pertain to the postage for mailing documents in electronic format. Estimating these costs is problematic because the costs would vary depending on the size of the document production (e.g. one binder of documents vs. numerous boxes of paper) and the media type (e.g., compact disk (CD) or digital video disk (DVD)) chosen to submit documents. Currently, we cannot identify how many documents will be submitted per response.

Some sample postage costs are shown for different types of packages:

- 10 CDs in a flat envelope weighing 30 ounces: Approximately $8 using first class business mail,
- Five-pound parcel containing paper documents: Approximately $12 using business parcel post mail and delivering to the furthest delivery zone,
- Ten-pound parcel containing paper documents: Approximately $17 using business parcel mail and delivering to the furthest delivery zone, and
- Fifty-pound parcel containing paper documents: Approximately $52 using business parcel post mail and delivering to the furthest delivery zone.

This estimate is based upon: (1) Ninety three submissions (80% of 116 submissions) being submitted by mailing an average of 10 CDs per envelope (93 x $8 = $744) and (2) Twenty three submissions (20% of the 116 submissions) being submitted by mailing a package of paper documents weighing an average of 50 pounds (23 x $52 = $1,196.) Therefore, we estimate the total capital costs associated with this document submission to be $1,940.

Dated: July 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–17607 Filed 7–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0356]

Agency Information Collection Activities; Proposed Collection; Comment Request; Designated New Animal Drugs for Minor Use and Minor Species

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 the paperwork associated with designation under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004.

DATES: Submit either electronic or written comments on the collection of information by September 20, 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 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, 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,