ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)
Selected women for exploratory focus groups	Exploratory Focus Group Guide	72	1	2
Selected women for message testing focus groups.	Message Testing Focus Group Guide	54	1	2

Dated: October 19, 2010.

Carol E. Walker,

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

[FR Doc. 2010–26878 Filed 10–22–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0542]

Agency Information Collection Activities; Proposed Collection; Comment Request; Information Request Regarding Dissolvable Tobacco Products

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 an information request regarding the use of dissolvable tobacco products.

DATES: Submit either electronic or written comments on the collection of information by December 27, 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 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 Dissolvable Tobacco Products

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C 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 required the Secretary of Health and Human Services (the Secretary) to establish a Tobacco Products Scientific Advisory Committee (TPSAC). Section 907(f) of the Tobacco Control Act requires the TPSAC to submit a report and recommendations to the Secretary on the impact of the use of dissolvable tobacco products on the public health, including such use among children. To ensure a comprehensive review of this issue, FDA is requesting tobacco industry documents and information to support the work of TPSAC. Under section 907(f), TPSAC must submit its report and recommendations to the Secretary within 2 years of its formation, or March 23, 2012.

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 pertaining to documents and underlying scientific and financial information relating to research, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on a specified set of topics. For the purposes of this request, "research" may include, but is not limited to, focus groups, surveys, experimental clinical studies, post-marketing surveillance, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices. Topics for which information relating to dissolvable tobacco products is requested are marketing research; marketing practices; effectiveness of marketing practices; and health, toxicological, behavioral, and physiological effects. FDA's request for documents related to dissolvable tobacco products includes, but is not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing, and also to the components, parts, or accessories of such products.

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

TABLE 1—ESTIMATE OF ONE-TIME REPORTING BURDEN[1]

Activity	Number of respondents	Annual frequency per response	Total average annual responses	Hours per response	Total hours
Providing negative response to request for dissolvable tobacco product documents	110	1	110	0.50	55
Submission of dissolvable tobacco products	10	1	10	230	2,300
Total	120	.....	120	.....	2,355

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

These burden estimates were derived by taking into consideration FDA's experience with document production, experience with submissions pertaining to other tobacco product-related information collections, and comments received in response to other tobacco product-related information collections. FDA is limiting the burden on respondents by only requesting documents on specific topics that will have utility for FDA. FDA is requesting the final version of documents or the most recent draft in the absence of a final document. Also, publically available published abstracts, editorials, letters, and manuscripts are not being requested, although FDA would appreciate a list of such publications. Information responsive to this section 904(b) information request that has been previously provided to FDA under the FD&C Act or other letter requests does not have to be resubmitted as long as the document is fully referenced. FDA believes that the number of documents being requested in this information collection will be limited due to the estimated small number of respondents and the relatively shorter amount of time these tobacco products have been in existence compared to other tobacco products.

FDA estimates that there are approximately 120 tobacco product manufacturers who may be affected by this collection of information. Of the total number of manufacturers, FDA estimates that most manufacturers (110) will not have documents which will be responsive to this section 904(b) request and that they will only need to send a letter notifying the FDA's Center for Tobacco Products that they have no documents to report. FDA anticipates it should take no longer than 30 minutes to draft such a response and send to FDA. The total one-time hourly burden to submit this letter to FDA is estimated to be 55 hours (30 minutes × 110 manufacturers).

FDA estimates that there are approximately 10 tobacco product manufacturers who may have documents meeting the criteria of this information collection request. Because the volume of responsive documents each of these respondents may have will likely vary, the corresponding time burden for each respondent to satisfy this information collection request will also vary. Therefore, FDA estimates that these 10 respondents will average approximately 230 hours each to satisfy the requirements of this section 904(b) request. The total one-time hourly burden to locate and send documents meeting the requirements of this request is estimated to be 2,300 hours (230 hours × 10 manufacturers). The total one-time hourly burden for this collection of information is 2,355 hours (55 hours + 2,300 hours).

Dated: October 19, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–26830 Filed 10–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0411]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

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 November 24, 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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0609. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables—(OMB Control Number 0910–0609)—Extension

Fresh-cut fruits and vegetables are fruits and vegetables that have been processed by peeling, slicing, chopping, shredding, coring, trimming, or mashing, with or without washing or other treatment, prior to being packaged for consumption. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or mashing, the high moisture content of the product, the absence of a step lethal