ESTIMATED ANNUALIZED BURDEN TABLE

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-administered questionnaire	Medicare beneficiaries	500	1	25/60	208
Total		500	.....	.....	208

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2010–3071 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0074]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in 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, 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 proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and to listing of ingredients in tobacco products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit written or electronic comments on the collection of information by April 19, 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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910–0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by, among other things, 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 905(b) of the act (21 U.S.C. 395(b)), as amended by the Tobacco Control Act, requires that "every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products * * *" register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(i)(1) of the act, as amended by the Tobacco Control Act, requires that all registrants "shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution," along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit "a listing of all ingredients, including tobacco, substances, compounds, and additives that are * * * added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand." Since the Tobacco Control act was enacted on June 22, 2009, the information required under section 904(a)(1) must be submitted to FDA by December 22,

2009, and include the ingredients added as of the date of submission. Section 904(c) of the act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA's receipt of submissions. FDA also developed paper forms (FDA Form 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and FDA Form 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at *http://www.fda.gov/tobacco*.

On September 1, 2009 (74 FR 45219), FDA published notice in the **Federal Register** announcing that a proposed collection of information had been submitted to OMB for emergency processing under the Paperwork Reduction Act of 1995. On September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. On October 13, 2009 (74 FR 52495), FDA published a notice reopening the comment period until October 26, 2009. Based on comments indicating that the burden estimates were too low, FDA has adjusted its original burden estimates. FDA has adjusted its burden estimate for registration and product listing for owners and operators of domestic establishments under section 905 of the act from 0.75 hours per response to 3.75 hours per response. FDA has adjusted its burden estimate for listing of ingredients under section 904 of the act from 0.75 hours per response to 3.0 hours per response. FDA also decreased the number of respondents for listing of ingredients under section 904 from 100,000 to 11,000 in response to comments that this estimate was too high. FDA also added the activity of applying for a Dun and Bradstreet D-U-N-S number to the burden of this information collection for those who chose to use eSubmitter.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
Registration and Product Listing for Owners and Operators of Domestic Establishments	100,000	1	100,000	3.75	375,000
Listing of Ingredients	11,000	1	11,000	3.0	33,000
Obtaining a Dun and Bradstreet D-U-N-S Number	1,550	1	1,550	0.5	775
Total	112,550		112,550		408,775

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

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3031 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0434]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff: Humanitarian Device Exemption Regulation: Questions and Answers; Availability

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 March 22, 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 Guidance for Humanitarian Device Exemption Holders, Institutional