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.

Title: Tobacco Health Document Submission (OMB Control Number 0910–0654)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Public Law 111–31) into law. The Tobacco Control Act granted 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. Among its many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products.

Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) of the act must be submitted to FDA beginning December 22, 2009.

FDA issued a draft guidance document entitled, "Tobacco Health Document Submission" on December 28, 2009 (74 FR 68629) to assist persons making certain document submissions to FDA under section 904(a)(4) of the act. While electronic submission of tobacco health documents is not required, FDA designed the eSubmitter application as an alternative for mailing documents. This electronic 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 is developing a paper form (FDA Form 3743) as an alternative submission tool. Both the eSubmitter application and the paper form can be accessed at *http://www.fda.gov/tobacco* once they are complete.

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. On January 7, 2010, FDA received emergency approval for this information collection. Based on comments indicating that the burden estimate was too low, FDA has adjusted its original burden estimate from 1.0 hour per response to 200 hours per response. FDA also increased the annual frequency per response from 1 to 4 (quarterly). FDA is maintaining the original estimate of the number of respondents at 10. FDA is basing its estimates on the total number of tobacco firms it is aware of, its experience with document production, and comments received in response to the draft guidance document published on December 28, 2009.

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 Responses	Hours per Response	Total Hours
Tobacco Health Document Submission	10	4	40	200	8,000

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

Dated: April 14, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8976 Filed 4–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0033]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance

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 May 20, 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@eop.gov*. All comments should be identified with the OMB control number 0910–0449. Also include the FDA 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, email: *Daniel.Gittleson@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.

Postmarket Surveillance—21 CFR Part 822 (OMB Control Number 0910–0449)—Extension

Section 522(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in §§ 822.15 to 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with § 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products.

Explanation of Reporting Burden Estimate

The burden captured in table 1 of this document for each of these responses is based on the data available in FDA's internal tracking system for 2009. There was not an internal tracking system prior to 2009. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because "it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument." (5 CFR 1320.3(h)(1)).

Explanation of Recordkeeping Burden Estimate

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Devices Act. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 21 manufacturers (3 to 4 added each year) and 30 investigators (3 per surveillance plan). After 3 years, FDA would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued.

In the **Federal Register** of February 5, 2010 (75 FR 6036), FDA published a 60–day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
822.9 and 822.10	21	1	21	120	2,520
822.21	5	1	5	40	200
822.28	5	1	5	8	40
822.29	1	1	1	40	40
822.30	1	1	1	40	40
822.38	40	1	40	40	1,600
Total					4,440

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Record	Hours per Records	Total Hours
822.31	21	1	21	20	420
822.32	63	1	63	5	315
Total					735

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

Dated: April 14, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–8977 Filed 4–19–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI); Correction Notice

The **Federal Register** notice published on March 3, 2010 (75 FR 9902) announcing the proposed collection and comment request for the project titled, "The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)" was submitted with errors. The burden table did not take into account the time related to complete the Phase III CATI as well as several telephone calls to schedule appointments and to follow up with instructions regarding the biospecimens collection. The corrected annual reporting burden is as follows:

TABLE A.12–1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent	Instrument	Estimated annual number of respondents	Frequency of response	Average time per response minutes/hour	Annual burden hours
Private Applicators, Spouses, Commercial Applicators.	Phase III Telephone Interview & Buccal Cell Scripts.	150	1	5/60 (0.083)	12.50
Private Applicators, Spouses, Commercial Applicators.	Phase III CATI	150	1	35/60 (0.583)	87.50
Private Applicators, Spouses, Commercial Applicators.	Phase III Buccal Cell Reminder, Missing or Damaged Scripts.	150	1	5/60 (0.083)	12.50
Private Applicators	BEEA CATI Screener	960	1	20/60 (0.33)	320.00
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 1.	310	1	20/60 (0.33)	5.17
Private Applicators	BEEA Schedule Home Visit Script.	10	3	5/60 (0.33)	2.50
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 3.	10	3	≤ 20/60 (0.33)	10.00
Total		1740			450.17

Dated: April 14, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–9098 Filed 4–19–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0600]

Guidance for Industry on Tobacco Health Document Submission; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Tobacco Health Document Submission." The guidance document is intended to assist persons making certain document submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Tobacco Health Document Submission" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), 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: Beth Buckler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 1–877–287–1373, *Beth.Buckler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 28, 2009 (74 FR 68629), FDA announced the availability of a draft guidance entitled "Tobacco Health Document Submission." The agency considered received comments as it finalized this guidance. The guidance document is intended to assist persons making certain document submissions to FDA under the Tobacco Control Act (Public Law 111–31).

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 904(a)(4) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological,