

Dated: April 14, 2010.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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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

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Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Institutes of Health.
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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,