DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0867]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents

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 a 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 the Experimental Study on the Public Display of the List of Harmful and Potentially Harmful Tobacco Constituents. This study is being conducted in support of the provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) that requires FDA to publish in a format that is understandable and not misleading to a lay person and to place on public display the list of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

DATES: Submit either electronic or written comments on the collection of information by February 13, 2012.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *daniel.gittleson@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.

Experimental Study on the Public Display of the List of Harmful and Potentially Harmful Tobacco Constituents (OMB Control Number—0910–New)

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 904(d)(1) of the FD&C Act states, ''Not later than 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall publish in a format that is understandable and not misleading to a lay person, and place on public display (in a manner determined by the Secretary) the list [of harmful or potentially harmful constituents] established under [section 904(e)]'' of the FD&C Act. Section 904(e) of the FD&C Act directs FDA to establish ''a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand, and by quantity in each brand and subbrand.'' On January 31, 2011, FDA announced the availability of a final guidance representing the Agency's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' (see 76 FR 5387). On August 12, 2011, FDA published a notice in the **Federal Register** requesting comment issues related to the establishment of the HPHC list (see 76 FR 50226).

FDA intends to conduct research with consumers to help inform decisions about how to implement section 904(d)(1) of the FD&C Act and to provide information about how consumers understand information about HPHCs. The research goals are to evaluate the impact of different list formats on the public's ability to understand HPHC information, and to assess the potential for certain unintended consequences resulting from exposure to the lists. The impact of different list formats will be measured by evaluating respondents' understanding of the following concepts: (1) There are more than 4,000 chemicals in tobacco products and tobacco smoke; (2) the chemicals come from the tobacco leaf itself, how it is processed, and different parts of a tobacco product such as the tobacco smoke, glues, inks, paper, or additives; (3) for smokeless products, many of the chemicals come from the tobacco leaf itself; for smoked products, many of the chemicals come from burning the tobacco leaf; (4) Federal law requires tobacco companies to test their tobacco products and smoke for the chemicals on this list; (5) each tobacco product brand and subbrand has its own separate list of chemicals; (6) science has linked the chemicals on these lists to health problems or potential health problems; (7) these lists do not include necessarily all of the health problems that may be caused by the tobacco product; (8) these lists do not necessarily include all of the chemicals in the tobacco product that may be harmful; (9) the amount of a chemical listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (10) the number of chemicals listed for a specific tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (11) the number of possible health outcomes listed for a tobacco product does not necessarily indicate the likelihood of experiencing a health problem; (13) the number of chemicals listed for a specific health problem does

not necessarily indicate the likelihood of experiencing a health problem; (13) when a chemical is listed without a quantity it may mean that a manufacturer has not yet tested its products for that chemical; and/or that a test was conducted but it was not sensitive enough to measure the amount of chemical in the product; and/or that a way to test for that chemical is still being developed. Unintended consequences will be assessed by measuring respondents' susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, risk perceptions about tobacco use, and emotional reactivity.

FDA proposes to conduct an experimental study with current smokers aged 15 years and older, former smokers aged 15 years and older, and nonsmokers aged between 13 and 25 years who may be susceptible to initiation of smoking. Data will be collected from members of an Internet panel. The study will include an oversampling of subjects with limited health literacy. Participation in the experimental study is voluntary. The information collected from the study is necessary to inform the Agency's efforts to implement the requirement of the FD&C Act to place on public display a list of HPHCs in tobacco products and tobacco smoke in a format that is understood and not misleading to a lay person, and is expected to provide information that may inform Agency communications about HPHCs. The data obtained from this study is one factor that will be used to inform FDA's decisionmaking regarding the public display of the list of HPHCs required under section 904(d)(1) of the FD&C Act. By evaluating respondents' understanding of the concepts listed previously in this document we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5	30
Screener	10,000	1	10,000	0.0167	167
Experimental Survey	3,000	1	3,000	0.5	1,500
Total	13,060				1,697

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 10,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.0167 hours), for a total of 167 hours. Three thousand respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,500 hours. The total estimated burden is 1,697 hours.

Dated: December 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32026 Filed 12–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

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 January 13, 2012.

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 0910–0374. 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.

Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of