DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0075]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 9, 2015, the Agency submitted a proposed collection of information entitled ''Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived From Genetically Engineered Plants'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0807. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01786 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1855]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products

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 3, 2016.

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–NEW and title ''Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Experimental Studies on Consumer Perceptions of Modified Risk Tobacco Products OMB Control Number 0910–NEW

FDA's Center for Tobacco Products proposes to conduct experimental studies to develop generalizable scientific knowledge to help inform its implementation of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k), wherein FDA will be evaluating information submitted to the Agency about how consumers understand and perceive tobacco products marketed as modified risk tobacco products (MRTPs). Section 911 of the FD&C Act authorizes FDA to grant orders to persons to allow the marketing of MRTPs. The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. FDA must issue an order authorizing the marketing of an MRTP if the Agency determines that the product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(1) of the FD&C Act).

FDA may also issue an order authorizing the marketing of an MRTP that reduces or eliminates exposure to a harmful substance if, among other requirements, the Agency determines that the order would be appropriate to promote the public health, the issuance of the order is expected to benefit the population as a whole taking into account both users and nonusers of tobacco products, and the existing evidence demonstrates that a measurable and substantial reduction in morbidity and mortality among individual tobacco users is reasonably likely to be shown in subsequent studies (section 911(g)(2) of the FD&C Act). In addition, section 911 requires that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all of the diseases and health related conditions associated with the use of tobacco products (section 911(h)(1) of the FD&C Act). The proposed research will inform the Agency's efforts to implement the provisions of the FD&C Act related to MRTPs.

FDA proposes to conduct experimental studies in order to develop generalizable scientific information to better understand how consumers perceive and understand these products, how exposure to claims about modified risk or exposure influence intentions to try or purchase the product, and how individual characteristics such as current tobacco use and/or brand loyalty might influence these outcomes. Moreover, information from the experimental studies may assist FDA to determine the appropriate methods and

measures for gathering such information from consumers.

The impact of different claims pertaining to modified risk or exposure on understanding, perceptions, and use intentions will be evaluated by conducting a series of three studies that, in turn, will examine: The impact of claims about cigarette (Study 1) or smokeless tobacco products (Study 2) among young adult and adult current, former, or never users of tobacco; and the impact of claims on adolescents currently using, or susceptible to using, tobacco (Study 3). All three studies will assess individual-level factors that might influence the impact of claims on consumer responses, including: Brand loyalty, tobacco use history and behavior, concerns about health risks, and openness to new products.

Across all studies, participants will be randomized to either see modified risk claims or not (control condition). In Studies 1 and 2, modified risk claims will be displayed on mock tobacco product packages and ads. For ethical reasons, adolescents (Study 3) will see modified risk claims displayed as statements alone, not attached to product packaging or ads. Consumer reactions to claims will be evaluated by measuring constructs such as: Understanding of the modified risk information in the claims, perceptions of harm and risk, beliefs about the product, quit intentions, and intention to try or purchase the product.

In the **Federal Register** of November 19, 2014 (79 FR 68888), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, however only two were PRA related.

(Comment) One commenter critiqued the inclusion of items assessing brand loyalty, asserting such constructs have ''no practical utility'' for MRTPA review and is beyond the FDA's statutory authority because it is not mentioned in the FD&C Act.

(Response) FDA does not agree. Although concepts such as ''brand loyalty'' are not specifically mentioned in the FD&C Act, FDA seeks understanding of how attitudes toward one's preferred brand(s) may affect perceptions and understanding of modified risk information (section 911(h)(1)). The goal of the present experiments is to understand how consumers react to RM and EM claims, in order to inform FDA's ability to evaluate MRTPAs. Brand loyalty is widely regarded as an important driver of consumer behavior (Ref. 1). Moreover, psychological theory and evidence suggests that the source of information can affect how that information is processed—including whether or not it is perceived as believable and is persuasive (Ref. 2). Thus, consumers' brand attitudes are highly relevant to understanding how they interpret and respond to claims made by that brand. To omit this possible influence from our analyses would, in our assessment, limit our ability to fully understand consumer perceptions of MRTPs.

(Comment) One commenter suggested that to assess the variable ''purchase interest,'' FDA should assign a hypothetical price to the product being studied.

(Response) FDA acknowledges that price plays an important role in consumers' purchasing decisions. However, examination of the role of price is beyond the scope of the present studies. The experimental design of this study will enable comparisons between experimental conditions on intentions to use the product; thus, rather than evaluating absolute levels of interest, results will examine relative levels of interest across experimental conditions. Thus, the measure of intentions to use the product will assess consumer interest in the product without regard to cost.

(Comment) One commenter noted that Study 1 proposes to focus on conventional cigarettes and asks how FDA proposes to address the issue of novel devices/products when considering consumer perceptions?

(Response) FDA agrees that the current studies are not designed to assess interest in novel devices/products. Addressing questions related to consumer perceptions of novel devices/products, and reactions to claims about those products, is beyond the scope of the current set of studies.

(Comment) One commenter asked for specificity regarding how FDA will define susceptibility to tobacco use among the adolescents in Study 3.

(Response) FDA plans to use items from Pierce and colleagues (1996) to identify adolescents who are susceptible to using tobacco. These items are: (1) Do you think that you will smoke a cigarette soon? (2) Do you think you will smoke a cigarette at any time in the next year? and (3) If one of your best friends were to offer you a cigarette, would you smoke it? Response options are: (1) Definitely yes; (2) Probably yes; (3) Probably not; and (4) Definitely not. A respondent who selects a response of 1, 2, or 3 to any of these items is classified as susceptible.

(Comment) One commenter sought clarification regarding which health warnings will be used (on the study stimuli) alongside the claims and how FDA intends to address the balance between MRTP claims and warnings.

(Response) Study stimuli-images of tobacco product packages and ads-will display the warning labels currently mandated for each product category. The warnings will be rotated (between participants) so that all mandated warnings are used. Because the current studies are not intended to examine the relationship between warnings and claims (including potential interactions between the two), warning label assignment will not be an experimental factor in the study design. Instead, the warnings will be rotated throughout all conditions to control for any differences between them (alone or in combination with a particular claim).

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
Adult Screener	24,000	1	24,000	0.03 (2 minutes)	720
Study 1 (Adults)	1,800	1	1,800	0.333 (20 minutes)	599
Study 2 (Adults)	600	1	600	0.333 (20 minutes)	200
Total Adult Hours					1,519
Youth Screener	6,000	1	6,000	0.03 (2 minutes)	180
Study 3 (Youth)	600	1	600	0.333 (20 minutes)	200

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total Youth Hours					380
Total Hours					1,899

[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 research that is similar to this proposed study. Approximately 30,000 respondents will complete a screener to determine eligibility for participation in a study, estimated to take approximately 2 minutes (0.03 hours), for a total of 900 hours for screening activities. Three thousand respondents will complete a full study, estimated to last 20 minutes (0.333 hours), for a total of 999 hours for completion of both adult studies and 1 youth study. The estimated total hour burden of the collection of information is 1,899 hours.

References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.*

1. Keller, Kevin L. and Donald R. Lehman, ''Brands and Branding: Research Findings and Future Priorities,'' *Marketing Science,* vol. 25, no. 6, pp. 740–759, 2006.
2. Eagly, Alice H. and Shelly Chaiken, ''Process Theories of Attitude Formation and Change: Reception and Cognitive Responding,'' *The Psychology of Attitudes,* Chapter 6, Harcourt Brace Jovanovich College Publishers, 1993.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01788 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Medical Imaging Investigations.
Date: February 18, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484; *mohsenim@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Diseases and Pathophysiology of the Visual System Study Section.
Date: February 25–26, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.
Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301–435–1265; *gordiyenkon@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group, Cancer Immunopathology and Immunotherapy Study Section.
Date: February 25–26, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.
Contact Person: Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301–435–0198; *shawdeni@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group, Tumor Progression and Metastasis Study Section.
Date: March 2–3, 2016.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.
Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718; *jakobir@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Alcohol, Drugs and Neurotoxicology.
Date: March 2–3, 2016.
Time: 8:00 a.m. to 12:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119; *selmanom@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–13–327: Innovative Molecular Analysis Technology Development for Cancer Research and Clinical Care.
Date: March 2, 2016.
Time: 11:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 594–2414; *huzhuang@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846– 93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 27, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–01818 Filed 2–1–16; 8:45 am]

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