

**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](mailto: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.*

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**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 [oir\\_submission@omb.eop.gov](mailto:oir_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](mailto: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