

petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA-2013-S-0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 7, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-08362 Filed 4-10-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0090]

#### **Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval; Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval.” This guidance clarifies FDA’s current policy on balancing premarket and postmarket data collection during the Agency’s review of premarket approval applications (PMA). Specifically, this guidance outlines how FDA considers the role of postmarket information in determining the appropriate type and amount of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of safety and effectiveness. FDA believes this guidance will improve patient access to safe and effective medical devices that are important to public health by improving the predictability, consistency, transparency, and efficiency of the premarket process.

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

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments 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:**

Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993-0002, 301-796-5178; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002.

**SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA has long applied postmarket controls as a way to reduce premarket data collection, where appropriate, while assuring that the statutory standard for approval of reasonable assurance of safety and effectiveness is still met. The right balance of premarket and postmarket data collection facilitates timely patient access to important new technology without undermining patient safety.

In this guidance, FDA describes existing statutory requirements under the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and FDA policies that support the policy on balancing premarket and postmarket data collection during review of PMAs. In addition, FDA clarifies how the

Agency considers postmarket data as part of the benefit-risk framework described in FDA’s guidance “Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications,” issued on March 28, 2012. This guidance provides a resource for industry and FDA staff on how FDA determines when it is appropriate for a sponsor of a PMA to collect some data (clinical or non-clinical) in the postmarket setting, rather than premarket.

A draft of this guidance was made available in the **Federal Register** on April 23, 2014, and the comment period closed July 22, 2014. Changes between the draft and final versions of this guidance include an increased focus on patient outcomes and additional examples to help industry better understand when it may be appropriate to shift data collection from the premarket to postmarket setting. The final guidance also recognizes the potential for use of registry data to satisfy post-approval study requirements.

#### **II. Significance of Guidance**

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on balancing premarket and postmarket data collection for devices subject to premarket approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

#### **III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of “Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1833 to

identify the guidance you are requesting.

#### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; the collection of information in 21 CFR part 860, subpart C have been approved under OMB control number 0910–0138; and the collections of information in the guidance document regarding requests for feedback on medical device submission have been approved under OMB control number 0910–0756.

#### V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 7, 2015.

**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–2294]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign

**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 May 13, 2015.

**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 “Evaluation of the Food and Drug Administration's ‘Fresh Empire’ Multicultural Youth Tobacco Prevention Campaign.” 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.

#### Evaluation of the Food and Drug Administration's 'Fresh Empire' Multicultural Youth Tobacco Prevention Campaign (OMB Control Number 0910–NEW)

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco

products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing a youth-targeted public education campaign (‘Fresh Empire’) to help prevent tobacco use among multicultural youth and thereby reduce the public health burden of tobacco. The campaign will feature events, advertisements on television and radio and in print, digital communications including social media, and other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information needed to evaluate FDA's ‘Fresh Empire’ multicultural youth tobacco prevention campaign. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to evaluate the effectiveness of its multicultural youth tobacco prevention campaign through an outcome evaluation study that will be designed to follow the multiple, discrete waves of media advertising planned for the campaign.

The outcome evaluation study consists of a pre-test survey of multicultural youth aged 12 to 17 before campaign launch. The pre-test survey will be followed by ongoing cross-sectional surveys of the target audience of youth beginning approximately 3 months following campaign launch. Information will be collected about youth awareness of and exposure to campaign events and advertisements and about tobacco-related knowledge, attitudes, beliefs, intentions, and use. Information will also be collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be recruited from two sources: (1) A sample drawn from 30 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation studies and (2) targeted social media