

outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS-10443 (OMB control number: 0938-1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 14,871; *Total Annual Responses:* 59,484; *Total Annual Hours:* 19,184. (For policy questions regarding this collection contact Sarah Fulton at 410-786-2749.)

Dated: March 15, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-7040-N2]

Health Insurance MarketplaceSM, Medicare, Medicaid, and the Children's Health Insurance Program; Cancellation of the March 23, 2016 Advisory Panel on Outreach and Education Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Cancellation of meeting.

SUMMARY: On February 25, 2016, we published a **Federal Register** notice (81 FR 9483) announcing a new meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel), which was scheduled for Wednesday, March 23, 2016. This notice announces the cancellation of the March 23, 2016 meeting.

FOR FURTHER INFORMATION CONTACT:

Abigail Huffman, Designated Federal Official, Office of Communications, CMS, 7500 Security Boulevard, Mail Stop S1-05-06, Baltimore, MD 21244, 410-786-0897, email

Abigail.Huffman1@cms.hhs.gov.

Additional information about the APOE is available on the Internet at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.html>. Press inquiries are handled through the CMS Press Office at (202) 690-6145.

Dated: March 15, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements

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 April 18, 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. All comments should be identified with the OMB control number 0910-New and title "Quantitative Information in Direct-to-Consumer Television Advertisements." 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.

Quantitative Information in Direct-to-Consumer Television Advertisements OMB Control Number 0910—NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

A previous FDA study found that simple quantitative information could be conveyed in direct-to-consumer (DTC) television ads in ways that increased consumer's knowledge about the drug (OMB control number 0910-0663, "Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs") (Ref. 1). However, this research only tested simple information (e.g., one clinical trial, comparison to placebo). Drug information can be much more complicated (e.g., complicated endpoints, multiple study arms). The