

including benefits across a broad range of activities ranging from athletics to more routine lifestyle activities, such as reading, watching TV, and driving; improves vision on average by 31% and two lines on the Snellen eye chart, and improves contrast sensitivity by 100%; and reverses, delays, or corrects aging eye or presbyopia, including, but not limited to, by improving night vision, improving users' ability to read in dim light, and diminishing the need for glasses or other visual aids. The complaint also alleges that the respondents violated Sections 5(a) and 12 by making the false or misleading representation that scientific testing proves that Ultimeyes improves vision in the above ways.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The order applies to marketing claims for any Covered Product or Service, defined as any Device within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. 52, 55, or any program or service that is: (1) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (2) intended to affect the structure or any function of the body of man or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes. As additional fencing-in relief, the order requires the respondents to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that it conducts or sponsors on any Covered Product or Service.

Part I prohibits any representation that a Covered Product or Service improves users' vision, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing of the Covered Product or Service that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall (1) be randomized, double-blind, and adequately controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, the respondents

must maintain all underlying or supporting data that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part II prohibits any representation about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or Service, unless it is non-misleading and supported by competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons; and that are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of human clinical tests or studies, the respondents must maintain all underlying or supporting data and documents that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part III, triggered when the human clinical testing requirement in Parts I or II applies, requires the respondents to secure and preserve all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test that is published in a peer-reviewed journal and that was not conducted, controlled, or sponsored by any respondent or by any supplier of the respondents. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part IV prohibits the respondents from misrepresenting, including through the use of a name, endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or that any benefits of a product, program, or service are scientifically proven.

Part V requires the respondents to disclose, when triggered by certain representations as to scientific support or endorsements in connection with the advertisement or sale of any product, program, or service, any material connections to any person that has

conducted, authored, or participated in any test, study, or research of the product, program, or service; and all material connections between a person providing an endorsement and respondents or any other person manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, program, or service.

Part VI provides the respondents will pay an equitable monetary payment of \$150,000 and contains other provisions related to the payment.

Part VII requires the respondents to provide sufficient customer information to administer redress.

Part VIII contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III, as well as order acknowledgments covered by Part IX.

Parts IX through XI require the respondents to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Part XII provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2015-24220 Filed 9-23-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10137 and CMS-10237]

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

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**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the

Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by October 26, 2015.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).
3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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. The term "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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare Prescription Drug Plan 2017 Contracts; *Use:* The information will be collected under the solicitation of proposals from prescription drug plans, Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD) plans, Cost Plan, PACE, and Employer Group Waiver Plan applicants. The information will be used by CMS to: Ensure that applicants meet CMS requirements and to support the determination of contract awards. Participation in the Part D program is voluntary. Only organizations that are interested in participating in the program will respond to the solicitation. The MA-PDs that voluntarily participate in the Part C program must submit a Part D application and successful bid. *Form Number:* CMS-10137 (OMB Control Number: 0938-0936); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 254; *Total Annual Responses:* 230; *Total Annual Hours:* 2,109. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C—Medicare Advantage and 1876 Cost Plan Expansion Application; *Use:* The information will be collected under the solicitation of Part C applications from Medicare Advantage, Employer Group Waiver Plan, and Cost Plan applicants and will be used by CMS to ensure that applicants meet CMS requirements, and to support the determination of contract awards. Participation is voluntary whereby only organizations that are interested in participating in the program will respond to the solicitation. Medicare Advantage (MA) organizations that offer integrated prescription drug and health care products (MA-PD

plans) that voluntarily participate in the Part C program must submit a Part D application and successful bid. *Form Number:* CMS-10237 (OMB Control Number: 0938-0935); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 566; *Total Annual Responses:* 566; *Total Annual Hours:* 21,926. (For policy questions regarding this collection contact Wanda Pigatt-Canty at 410-786-6177).

Dated: September 21, 2015.

**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-7038-N]

#### Health Insurance Marketplace, Medicare, Medicaid, and Children's Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), October 7, 2015

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

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Health Insurance Marketplace, Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This meeting is open to the public.

**DATES:** *Meeting Date:* Wednesday, October 7, 2015, 8:30 a.m. to 4:00 p.m. eastern daylight time (e.d.t.).

*Deadline for Meeting Registration, Presentations and Comments:* Wednesday, September 30, 2015, 5:00 p.m., e.d.t.

*Deadline for Requesting Special Accommodations:* Wednesday, September 30, 2015, 5:00 p.m., e.d.t.

**ADDRESSES:**

*Meeting Location:* U.S. Department of Health & Human Services, Hubert H.