

4. Entry and Efficiencies

Entry into the relevant market has not been, and would not be, timely, likely, or sufficient to deter or counteract the anticompetitive effects of the acquisition. Optical labs have limited short-term ability to switch from Valeant and Paragon, which supply the majority of their GP scleral buttons and GP general vision correction buttons, and 100 percent of their GP orthokeratology buttons. Optical labs might try to persuade eye care professionals to switch to a different material and brand, but ultimately the decision is made by the eye care professional, for whom such a change is costly and time-consuming.

Considerable entry barriers also arise from the FDA approval process. For GP orthokeratology buttons, the FDA premarket approval process takes several years because finished orthokeratology lenses worn overnight are Class III medical devices. For GP scleral and general vision buttons, the FDA premarket notification process likely requires at least one year, as the finished lenses incorporating such buttons are Class II medical devices.

We did not find any evidence of efficiencies that would outweigh the competitive concerns arising from the Paragon acquisition.

5. Consent Order

The proposed Consent Order requires Valeant to divest Paragon in its entirety no later than ten (10) days after the order date, to remedy the concerns raised by the acquisition and restore competition in the relevant markets by instituting Paragon as an independent, viable competitor to Valeant. The proposed Consent Order also requires Valeant to divest Pelican with Paragon to ensure continued access to FDA-approved vials for shipping its finished lenses.

The proposed Consent Order requires that Valeant must divest Paragon and Pelican to Paragon Companies LLC in an upfront transaction. Paragon Companies LLC is a newly created entity owned by Joe Sicari. Mr. Sicari was the president of Paragon prior to its acquisition by Valeant in May 2015.

The Commission may, at any time, appoint a Monitor with the power and authority to ensure that Valeant fulfills all obligations and responsibilities under the Consent Order and Divestiture Agreement.

The Consent Order will remain in effect for ten (10) years, and contains standard compliance and reporting requirements.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-16AOW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC I-Catalyst Program—New—Office of the Associate Director for Science, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Office of Technology and Innovation (OTI) within Office of the Associate Director for Science (OADS) is seeking approval for a new CDC generic clearance. OTI fosters innovative science and promotes the testing and implementation of innovative ideas that improve CDC's ability to have public health impact. To arm CDC staff with an expanded skill-set and tools to evaluate and translate their insights and ideas into solutions, CDC developed an experiential innovation curriculum called I-Catalyst based on the NSF I-Corp program. The program was created with the belief that innovation should be customer driven, be based on user research, and is something people at all levels of an organization can engage in.

The purpose of the I-Catalyst program is to teach CDC teams a process of discovering the issues and problems faced by their customers before considerable time and money is spent on a solution that may not be used. Each participating I-Catalyst project team will present with a unique customer problem for which they have a proposed solution. Participating project teams will go through a hypothesis-testing, scientific method of discovery to gather important insights about their customers and their needs.

Each individual collection will be a different problem for which a CDC team is designing a solution. The types of customers or stakeholders teams' interview will be detailed in each collection. For example, teams may interview government employees if the solution is intended to improve how government employees do their work. On the other hand, teams may interview individuals who work in industry and businesses if the problem is one experienced by external customers. This data collection covers qualitative information to be obtained through on-site, unstructured interviews with individuals who represent the customers or stakeholders CDC teams are attempting to serve or benefit.

It is expected that the program will help CDC teams generate information about their customers to help them make the case for key innovation investments to advance important public health solutions and innovations. The ultimate goal of the I-Catalyst program is to give CDC staff skills to successfully transfer knowledge into

value-based solutions that benefit society and broaden the agency’s impact. Participation in the I-Catalyst interviews is completely voluntary. A three-year approval is requested. There is no cost to respondents other than their time.

CDC anticipates 30 projects over the next three years. Each project team will interview their customers/stakeholders for an average of 30 minutes and maximum of 2 responses per respondent. Each team will interview approximately 50 respondents.

Approximately 1500 respondents will be interviewed. Of these respondents, approximately 40% of individuals will be internal CDC/ATSDR staff and 60% will be external partners, stakeholders, or customers. Annualized burden will be 500 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
External + Internal stakeholder/customers ...	Sample Interview Guide	500	2	30/60	500

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.
 [FR Doc. 2016-27421 Filed 11-14-16; 8:45 am]
 BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17CX; Docket No. CDC-2016-0108]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed project entitled “Reframing How We Talk About Alcohol: Public Perceptions of Excessive Alcohol Use Among Multiple Audiences.” CDC will seek a one-year approval for a new information collection request to assess the public’s perceptions and frames regarding alcohol use and its related harms, gain insights on the language the public uses when talking about excessive alcohol use, examine patient-provider communication about alcohol use, and evaluate the influence of other sources

of information on the public’s understanding of excessive alcohol use.

DATES: Written comments must be received on or before January 17, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0108, by any of the following methods:

- *Federal eRulemaking portal:*

Regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

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. In addition, the PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed

extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses); and (e) Assess information collection costs. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and use technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information, search data sources, and complete and review the collection of information; and to transmit or otherwise disclose the information.