

perceptions, and attitudes across various audience segments: those who engage in binge drinking, those who drink but not excessively, and those who abstain from drinking.

The focus group discussions will be analyzed using qualitative tools and leverage a structured approach to thematic analysis. Findings from this

information collection will guide the CDC Alcohol Program in the development and refinement of targeted messages to effectively communicate the problem of excessive alcohol use, and encourage support for effective prevention strategies. The ultimate goal of the subsequent messaging is a

reduction in binge drinking, which will in turn reduce alcohol-related injuries and deaths among adults.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annual burden hours are 132.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adults aged 21–64	Questionnaire/Screeners	288	1	5/60
	Focus Group	72	1	1.5
Total

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10171]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and

clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 17, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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.

3. Call the Reports Clearance Office at (410) 786–1326.

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

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS–10171 Collecting Benefit Coordination Data

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collecting Benefit Coordination Data; *Use:* This collection of information request coordinates Part D plan prescription drug coverage with other prescription drug coverage. The collected information will assist CMS, Part D

plans and other payers with coordination of prescription drug benefits at the point-of-sale and tracking of the beneficiary's True out-of-pocket (TrOOP) expenditures using the Part D Transaction Facilitator (PDTF). *Form Number*: CMS-10171 (OMB control number: 0938-0978); *Frequency*: Yearly and occasionally; *Affected Public*: Business or other for-profits; *Number of Respondents*: 62,438; *Total Annual Responses*: 891,777,634; *Total Annual Hours*: 5,201,718. (For policy questions regarding this collection contact Shelly Winston at 410-786-3694.)

2.

Dated: December 14, 2016.

William N. Parham, III,

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

[FR Doc. 2016-30432 Filed 12-16-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-E-3157]

Determination of Regulatory Review Period for Purposes of Patent Extension; TRULICITY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TRULICITY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by February 17, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 19, 2017. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows: June 19, 2017

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions)*: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-E-3157 for "Determination of Regulatory Review Period for Purposes of Patent Extension; TRULICITY." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and