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 August 11, 2014.

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.*

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: 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:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Use:* Form CMS–304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS–304a (Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS–304 and –304a (OMB control number: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 1,037; *Total Annual Responses:* 4,148; *Total Annual Hours:* 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS–R–144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS–368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS–368 and –R–144 (OMB control number: 0938–0582); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

3. *Type of Information Collection Request:* New collection (Request for a new control number); *Title of Information Collection:* The Predictive Learning Analytics Tracking Outcome (PLATO™); *Use:* The Predictive Learning Analytics Tracking Outcome (PLATO™) is a web-based application tool that will serve as the centerpiece of the advanced analytics initiative with the Centers for Medicare & Medicaid Services (CMS) and Health Integrity, LLC, the National Benefit Integrity Medicare Integrity Contractor (NBI MEDIC). Developed by Health Integrity, LLC and licensed for one of its contracts—the NBI MEDIC—PLATO™ utilizes a cutting-edge advanced analytics fraud detection process in conjunction with a state-of-the-art web-based user interface tool to present fraud and abuse lead information visually to Medicare Part D plan sponsors. Summary data, based on National Prescription Drug Event Data and actions from all Part D plan sponsors, is shared with law enforcement, CMS, NBI MEDIC, and Part D plan sponsors to review historic actions taken against providers who are enrolled in the Medicare Part D program, which will assist in detecting and preventing fraud, waste, and abuse. *Form Number:* CMS–10517 (OMB control number: 0938—New); *Frequency:* Monthly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 1,550; *Total Annual Responses:* 1,550; *Total Annual Hours:* 18,600. (For policy questions regarding this collection contact Delois Newkirk at 410–786–1247.)

Dated: July 3, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–16083 Filed 7–10–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

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 (PRA).

DATES: Fax written comments on the collection of information by August 11, 2014.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.'' 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.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007—(OMB Control Number 0910-New)

This guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. Grandfathered tobacco products are not considered new tobacco products and thus are not subject to premarket review. A grandfathered tobacco product may also serve as the predicate tobacco product in a Section 905(j) Report: Demonstrating Substantial Equivalence for Tobacco Products (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(1)(A)(i)).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the grandfathered status of a tobacco product under the guidance is not required and also on indications of interest of making such request. The number of hours to gather the evidence is FDA's estimate of how long it might take one to review, gather, and submit dated information if making a request for Agency determination. After further consideration of these estimates, FDA has reduced the number of hours to submit this information from 10 to 5 hours.

In the **Federal Register** of April 25, 2011 (76 FR 22903), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were submitted on FDA's estimates of the number of respondents or burden. FDA received three comments that generally addressed topics related to the recommendations of the guidance, including questions about the status of tobacco products that were in test markets in the United States as of February 15, 2007, and how much evidence should be submitted.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	150	1	150	5	750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based the estimates on information it received from interactions with the industry that 3 large manufacturers might submit as many as 25 packages of evidence annually, and other manufacturers might submit as many as 125 packages of evidence indicating that their tobacco product was commercially marketed in the United States as of February 15, 2007, for a total of 150 responses annually. FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. This is a reduction from FDA's original estimate of 10 hours per response. FDA estimates that it should take approximately 750 hours annually (150 responses times 5 hours for each response) to respond to this collection of information.

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16252 Filed 7–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0434]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HORIZANT and is publishing this notice of that determination as required by law. FDA has made the determination because of the