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]

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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

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 drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: 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 an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product HORIZANT (gabapentin enacarbil). HORIZANT is indicated for the treatment of moderate to severe primary Restless Legs Syndrome in adults. Subsequent to this approval, the USPTO received a patent term restoration application for HORIZANT (U.S. Patent No. 6,818,787) from XenoPort, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 2, 2012, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of HORIZANT represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HORIZANT is 2,277 days. Of this time, 1,459 days occurred during the testing phase of the regulatory review period, while 818 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 12, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 12, 2005.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 9, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for Horizant (NDA 22–399) was submitted on January 9, 2009.

3. *The date the application was approved:* April 6, 2011. FDA has verified the applicant's claim that NDA 22–399 was approved on April 6, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 882 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by September 9, 2014. 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 January 7, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16237 Filed 7–10–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0829]

Draft Guidance for Industry on Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act.'' On March 23, 2010, the Patient Protection and Affordable Care Act (ACA) was signed into law. The Secretary of Health and Human Services has delegated authority to FDA to issue guidance to identify the information to be submitted under section 6004 and oversee and make arrangements for the collection of such information. FDA is issuing this draft guidance to provide information to assist persons submitting drug sample information under ACA section 6004, and to advise industry of an updated compliance policy. This draft guidance revises the draft compliance policy guide issued on April 3, 2012.