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.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 9, 2014. Submit either electronic or written comments concerning the proposed collection of information by September 9, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th floor, Rm. 4147, Silver Spring, MD 20993, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karen Rothschild, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4282, Silver Spring, MD 20903, 301–796–3689, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20903, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

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 ACA was signed into law. Among its many provisions, section 6004 of the ACA amended the Social Security Act (SSA) by adding section 1128H (42 U.S.C. 1320a–7i). This new section required the submission of certain drug sample information to FDA not later than April 1 of each year, beginning April 1, 2012.

In particular, section 6004 requires reporting about drug sample requests and distributions from manufacturers and authorized distributors of record (ADRs) of applicable drugs (prescription drugs), which are defined in the ACA as drugs subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353(b)) for which payment is available under Title XVIII or the SSA or a State plan under Title XIX or XXI of the SSA (or a waiver of such plan). (See 42 U.S.C. 1320a–7i(b)(1).) The Secretary has delegated authority to FDA to issue guidance identifying the information to be submitted under section 6004, and to oversee and arrange for the collection of such information.

Section 6004 is not part of the Prescription Drug Marketing Act (PDMA) but must be read together with that act. Two of the terms used in section 6004 are defined by reference to the PDMA. In addition, the PDMA and its implementing regulations at 21 CFR part 203, subpart D (beginning at § 203.30 (21 CFR 203.30)) require the collection and maintenance of information that must be submitted under section 6004. For example, § 203.38(b) requires that a manufacturer or ADR *maintain* records of drug sample distribution for all samples distributed under section 503(d)(2) or 503(d)(3) of the FD&C Act that are sufficient to permit tracking of sample units to the point of the licensed practitioner. Under section 6004, manufacturers and ADRs must now *submit* much of the same information, aggregated as specified, to FDA.

Another example of how the PDMA and section 6004 are complementary is that the PDMA requires manufacturers and ADRs to collect signatures to ensure that drug samples are distributed on the request of authorized persons and that their receipt is accounted for by persons authorized to take responsibility for them. The purpose of this requirement is to ensure a tight chain of custody, which is why no person other than the practitioner or a specified designee (i.e., not a common carrier) may sign for receipt of drug samples. The requirement in section 6004 to report drug sample requests and distributions for each drug, aggregated by signature, is to ensure that FDA has the information needed to demonstrate compliance with this important PDMA provision.

In the **Federal Register** of April 3, 2012 (77 FR 20025), FDA issued a draft guidance for industry entitled ''Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act,'' concerning section 6004. In that draft guidance, FDA explained that the Electronic Submissions Gateway (the Gateway) was available and ready to receive submissions of drug sample information as required by section 6004. That guidance also stated FDA's temporary compliance policy with regard to those submissions, and FDA's intent to issue subsequent guidance with details to better assist persons submitting drug sample information under section 6004 and to advise industry of an updated compliance policy. FDA received comments on the guidance and on the use of the Gateway to submit the drug sample information required by section 6004. After carefully considering submitted comments, FDA has revised the draft guidance, adding more substantive information and announcing an updated compliance policy, and is reissuing it as a draft to facilitate public comment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on reporting drug sample information under section 6004 of the ACA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 that they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of

FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under section 6004 of the ACA, manufacturers and ADRs must submit the following drug sample information to FDA each year: (1) The identity and quantity of drug samples requested; (2) the identity and quantity of drug samples distributed; (3) the name, address, professional designation, and signature of any person who makes or signs for the request; and (4) any other category of information determined appropriate by the Secretary. The draft guidance clarifies the specific information that should be submitted under this provision and the manner in which that information should be submitted.

The draft guidance states that FDA's Gateway became available for drug sample reporting under 6004 in March 2012, and that FDA intends to continue the use of the Gateway for this purpose. The Gateway accepts submissions in XML format. Technical specifications for the data type and size for submitting each of the items listed previously may be found in the ACA Industry Submission Specifications User Guide, available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM297610.pdf.*

The Gateway requests that manufacturers and ADRs provide the following information, which is sufficient to comply with the reporting requirements set forth in section 6004 of the ACA:

- The year the sample was distributed to the provider;
- the type of business (i.e., either manufacturer or distributor);
- the business name of the manufacturer or distributor that distributed the drug sample;
- the trade name and dosage of the drug sample distributed;
- the total quantity of the drug requested by the practitioner during the calendar year;
- the total quantity of the drug distributed to the practitioner during the calendar year;
- the first name, last name, and middle initial of the practitioner;
- the practitioner's designation (i.e., M.D., D.O., P.A., or more);
- the street number, street name, city, state, and ZIP code address of the practitioner;
- an electronic affirmation that a signed written request for drug samples was received by the manufacturer or ADR from the licensed practitioner and is available to FDA upon request;
- an electronic affirmation that a signature of the requesting practitioner, or appropriate designee, acknowledging receipt of drug samples has been received by the manufacturer or ADR and is available to FDA upon request;
- the first name, last name, and middle initial of a practitioner's designee; and
- the address, including street number, street, city, state, and ZIP code of the designee.

Based on the current number of submissions since the enactment of section 6004 of the ACA, we estimate that annually a total of approximately 120 to 250 manufacturers or ADRs (''number of respondents'' in table 1) will submit the drug sample information specified, resulting in approximately 120 to 250 annual submissions (''total annual responses'' in table 1). We also estimate that preparing and submitting this information to FDA will take approximately 500 to 600 hours for each manufacturer or ADR (''hours per response'' in table 1). We base the burden hour estimate on information we obtained from two manufacturers who have submitted the drug sample information since the enactment of section 6004 of the ACA. We are using the upper end of these ranges to calculate the burden in table 1, and the burden hour estimate includes the time that may be needed to submit any followup or additional information to FDA. In addition, for purposes of this notice, FDA assumes that only manufacturers will submit the required information on behalf of all samples distributed, thereby excluding the need for ADRs to do so.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 6004 of the ACA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of drug sample information	250	1	250	600	150,000

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

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16238 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–D–0902]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions; Amendments and Easily Correctable Deficiencies Under the Generic Drug User Fee Amendments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.