Dated: June 3, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–2341]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TANZEUM 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 (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 9, 2016. 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 December 7, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2014–E–2341

For Determination of Regulatory Review Period for Purposes of Patent Extension; TANZEUM. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://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 *http://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 an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological product TANZEUM (albiglutide). TANZEUM is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the U.S. Patent and Trademark Office (USPTO) received a patent term restoration application for TANZEUM (U.S. Patent No. 7,141,547) from Human Genome Sciences, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of TANZEUM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for TANZEUM is 3,014 days. Of this time, 2,557 days occurred during the testing phase of the regulatory review period, while 457 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 15, 2006. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on January 15, 2006.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* January 14, 2013. The applicant claims January 11, 2013, as the date the biologics license application (BLA) for TANZEUM (BLA 125431) was initially submitted. However, FDA records indicate that BLA 125431 was received by FDA on January 14, 2013.

3. *The date the application was approved:* April 15, 2014. FDA has verified the applicant's claim that BLA 125431 was approved on April 15, 2014.

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 1,577 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). 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. To meet its burden, the petition must be timely (see **DATES**) and 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.

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

Dated: June 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13797 Filed 6–9–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reproductive and Environmental Health Network

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of a Single-Award Deviation from Competition Requirements for the Reproductive and Environmental Health Network.

SUMMARY: HRSA announces the award of an extension in the amount of $1,100,000 for the Reproductive and Environmental Health Network (REHN) cooperative agreement. The purpose of the REHN is to improve maternal and fetal health outcomes by providing evidence-based information on the safety of exposures in pregnancy and lactation. The extension will permit the Organization of Teratology Information Specialists (OTIS), the cooperative agreement awardee, during the budget period of 9/1/2016–8/31/2017, to continue to provide evidence-based information on the safety of exposures in pregnancy and lactation through individualized risk-assessments and counseling services, developing and disseminating the most current education to providers and the public, improving access to information for hard-to-reach populations, and supporting a national network of resources with centers accessible to each of the 10 HRSA regions.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Organization of Teratology Information Specialists.

Amount of Non-Competitive Awards: $1,100,000.

Period of Supplemental Funding: 9/1/2016–8/31/2017.

CFDA Number: 93.110.

Authority: Social Security Act, Title V, § 501(a)(2); (42 U.S.C. 701(a)(2)).

Justification: REHN activities are essential to achieving HHS Healthy People 2020 goals related to improving preconception care, preventing maternal morbidity and mortality, reducing infant mortality, and reducing health disparities in perinatal health. During this extension period of the budget period (9/1/2016–8/31/2017), MCHB plans to issue a new FOA that will align HRSA's work in this area with work funded by the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention's (CDC) through their jointly funded Pediatric Environmental Health Specialty Unit Program (PEHSU). Aligning REHN and PEHSU will result in a more comprehensive HHS initiative to expand access to services and maximize limited resources in this area. During this time, OTIS would continue to provide individualized risk-assessments and counseling services, developing and disseminating the most current education to providers and the public, improving access to information for hard-to-reach populations, and supporting a national network of resources with centers accessible to each of the 10 HRSA regions.

MCHB proposes to initiate a one-time 12 month extension for the budget period of 9/1/2016 to 8/31/2017 with $1,100,000 in FY 2016 funds to the OTIS REHN cooperative agreement. The extension would allow the OTIS to continue to provide evidence-based information on the safety of exposures in pregnancy and lactation through individualized risk-assessments and counseling services, developing and disseminating the most current education to providers and the public, improving access to information for hard-to-reach populations, and supporting a national network of