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]

BILLING CODE 4164–01–P

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

resources with centers accessible to each of the 10 HRSA regions.

FOR FURTHER INFORMATION CONTACT: Kathryn McLaughlin, MPH, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W08, Rockville, MD 20852, Phone: (301) 443–6829, Email: *KMcLaughlin@hrsa.gov.*

Dated: June 3, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–13784 Filed 6–9–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 9, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14A39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: National Practitioner Data Bank (NPDB) Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Health Centers.

OMB No. 0915–xxxx—New.

Abstract: The NPDB plans to collect data from hospitals, medical malpractice payers, health plans, and certain other health care entities [1] that are subject to NPDB reporting requirements to assist these entities in understanding and meeting their reporting requirements to the NPDB. The NPDB currently collects similar data from state licensing boards on a regular basis, and this information collection request would expand beyond current reporting activities to include hospitals, medical malpractice payers, health plans, and certain health care entities.

The NPDB began operation on September 1, 1990. The statutory authorities establishing and governing the NPDB are title IV of Public Law (Pub. L.) 99–660, the Health Care Quality Improvement Act of 1986, as amended, section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, codified as section 1921 of the Social Security Act, and section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, codified as section 1128E of the Social Security Act. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for NPDB implementation and operation resides in the Bureau of Health Workforce, Health Resources and Services Administration, Department of Health and Human Services (HHS).

The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information on medical malpractice payments, health-related civil judgments, adverse licensure actions, adverse clinical privileging actions, adverse professional society actions, and Medicare/Medicaid exclusions is collected from and disseminated to eligible entities such as licensing boards, hospitals, and other health care entities. It is intended that NPDB information should be considered with other relevant information in evaluating a practitioner's credentials.

The NPDB outlines specific reporting requirements for hospitals, medical malpractice payers, health plans, and health care entities; per 45 CFR 60.7, 60.12, 60.14, 60.15, and 60.16. These reporting requirements are further explained in chapter E of the NPDB e-Guidebook, which can be found at: *http://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp*.

Through a process called Attestation, hospitals, medical malpractice payers, health plans, and certain other health entities will be required to attest that they understand and have met their responsibility to submit all required reports to the NPDB. The Attestation process will be completely automated through the secure NPDB system (*https://www.npdb.hrsa.gov*), using both secure email messaging and system notifications to alert entities registered with the NPDB of their responsibility to attest. All entities with reporting requirements and querying access to the NPDB must register with the NPDB before gaining access to the secure NPDB system for all reporting and querying transactions.

Although the Attestation process and forms are new, the secure NPDB system currently used by hospitals, medical malpractice payers, health plans, and health care entities to conduct reporting and querying will not change, ensuring that these entities are familiar with the interface needed to complete the Attestation process. NPDB will ask these entities to attest their reporting compliance every 2 years. If the organization is responsible for privileging or credentialing individuals who provide services for other sites, those sites will be included in the Attestation process.

The Attestation forms will collect the following information: (1) Information regarding sub-sites and entity relationships; (2) contact information for the Attesting Official; and (3) a statement attesting whether or not all required reports have been submitted.

Need and Proposed Use of the Information: The NPDB engages in compliance activities to ensure the accuracy and completeness of the information in the NPDB. Through the Attestation process, the NPDB can better determine which hospitals, medical malpractice payers, health plans, and health care entities are meeting the reporting requirements, and which of

[1] Unless otherwise noted, the term ''health care entities'' refers to health centers whose access and reporting obligations are addressed in the NPDB statutory and regulatory requirements for health care entities. In this document, ''health center'' refers to organizations that receive grants under the HRSA Health Center Program as authorized under section 330 of the Public Health Service Act, as amended (referred to as ''grantees'') and Federally Qualified Health Center (FQHC) Look-Alike organizations, which meet all the Health Center Program requirements but do not receive Health Center Program grants. It does not refer to FQHCs that are sponsored by tribal or Urban Indian Health Organizations, except for those that receive Health Center Program grants.