a letter dated February 17, 2011, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of KALBITOR represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KALBITOR is 2,855 days. Of this time, 2,420 days occurred during the testing phase of the regulatory review period, while 435 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:* February 8, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 8, 2002.

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):* September 23, 2008. FDA has verified the applicant's claim that the biologics license application (BLA) for KALBITOR (BLA 125277/0) was initially submitted on September 23, 2008.

3. *The date the application was approved:* December 1, 2009. FDA has verified the applicant's claim that BLA 125277/0 was approved on December 1, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,645 days and 178 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 July 2, 2012. 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 October 24, 2012. 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 petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10518 Filed 5–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0114]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Victoza 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 Patents and Trademarks, 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 along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

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 Patents and Trademarks 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 recently approved for marketing the human drug product VICTOZA (liraglutide (rDNA origin)). VICTOZA 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 Patent and Trademark Office received a patent term restoration application for Victoza (U.S. Patent No. 6,268,343) from Novo Nordisk A/S, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 25, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Victoza represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Victoza is 3,370 days. Of this time, 2,757 days occurred during the testing phase of the regulatory review period,

while 613 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:* November 5, 2000. The applicant claims October 5, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 5, 2000, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* May 23, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for Victoza (NDA 22–341) was initially submitted on May 23, 2008.

3. *The date the application was approved:* January 25, 2010. FDA has verified the applicant's claim that NDA 22–341 was approved on January 25, 2010.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 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 July 2, 2012. 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 October 24, 2012. 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 petitions. It is only necessary to send one set of comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: April 16, 2012.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–10517 Filed 5–1–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Tomorrows Partnership for Children Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of a non-competitive one-year extension with funds for the National Healthy Tomorrows Technical Assistance Resource Center (U50).

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing a non-competitive one-year extension with funds for the National Healthy Tomorrows Technical Assistance Resource Center at the American Academy of Pediatrics (AAP). Up to $176,855 will be awarded over a one-year extended project period. The National Healthy Tomorrows Technical Assistance Resource Center provides support for the activities of the Healthy Tomorrows Partnership for Children Program (HTPCP), community-based grants that address priority issues determined by the community. Through a cooperative agreement, the Resource Center also offers consultation to HTPCP program participants to ensure successful implementation and sustainability of community-based initiatives; facilitates involvement of local partners such as pediatricians, State/local AAP chapters, State/local maternal and child health agencies, and other private sector partners in HTPCP projects to promote successful implementation of community-based maternal and child health initiatives; and conducts a national evaluation of HTPCP projects that assesses critical factors contributing to program sustainability, effectiveness and impact of community-based projects post HTPCP funding, and the ability of projects to develop meaningful evaluation and sustainability plans. A 2005 national evaluation found that 80 percent of HTPCP projects are fully or partially sustained 5 years post-Federal funding. The proposed extension with funds will allow the Maternal and Child Health Bureau (MCHB) to align the National Healthy Tomorrows Technical Assistance Resource Center with the National Center for Medical Home Implementation.

SUPPLEMENTARY INFORMATION: Recipient of record and intended award amount is:

Organization name	Cooperative agreement number	State	FY2011 Authorized funding level	FY2012 Estimated funding level
The American Academy of Pediatrics (AAP)	U50MC07618	IL	$176,855	$176,855

Amount of the Award: Up to $176,855 for one recipient over a one-year project period.

CFDA Number: 93.110.

Current Project Period: 9/1/2011 through 8/31/2012.

Period of Supplemental Funding: 9/1/2012 through 8/31/2013.

Authority: Title V of the Social Security Act, Section 501(a)(2), (42 U.S.C. 701 (a)(2)).

Justification

Over 75 percent of Healthy Tomorrows projects are involved in case management/care coordination or establishing a medical home in underserved and vulnerable communities. HTPCP has long encouraged Healthy Tomorrows projects involved in case management/care coordination or medical home to adopt the medical home model, so the combination of these investments achieves efficiencies. The National Healthy Tomorrows Technical Assistance Resource Center provides resources to grantees interested in medical home implementation, but has limited capacity to offer detailed technical assistance to grantees assessing the benefits and challenges of implementing a meaningful medical home in communities with finite resources. A strategic partnership with