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 PRISTIQ (desvenlafaxine sucinate). PRISTIQ is indicated for treatment of major depressive disorder. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PRISTIQ (U.S. Patent Nos. 6,673,838 and 7,291,347) from Wyeth, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PRISTIQ 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 PRISTIQ is 2,124 days. Of this time, 1,324 days occurred during the testing phase of the regulatory review period, while 800 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 act) (21 U.S.C. 355(i)) became effective*: May 9, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 9, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: December 22, 2005*. The applicant claims December 22, 2005, as the date the new drug application (NDA) for PRISTIQ (NDA 21–966) was initially submitted. However, FDA records indicate that the application initially submitted for PRISTIQ was NDA 21–992 and FDA has confirmed that NDA 21–992 was initially submitted on December 22, 2005.

3. *The date the application was approved*: February 29, 2008. FDA has verified the applicant's claim that PRISTIQ was approved on February 29, 2008. However FDA records indicate that it was NDA 21–992 that was approved.

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 17 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 November 1, 2010. 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 [*insert date 180 days after date of publication in the* **Federal Register**]. 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. It is no longer necessary to send three copies of mailed 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–21586 Filed 8–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0061]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ONGLYZA 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. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 ONGLYZA (saxagliptin). ONGLYZA 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 ONGLYZA (U.S. Patent No. 6,395,767) from Bristol-Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ONGLYZA 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 ONGLYZA is 2,794 days. Of this time, 2,397 days occurred during the testing phase of the regulatory review period, while 397 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 act) (21 U.S.C. 355(i)) became effective*: December 8, 2001. The applicant claims November 8, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 8, 2001, 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 act*: June 30, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for ONGLYZA (NDA 22–350) was submitted on June 30, 2008.

3. *The date the application was approved*: July 31, 2009. FDA has verified the applicant's claim that NDA 22–350 was approved on July 31, 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 application for patent extension, this applicant seeks 896 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 November 1, 2010. 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 [*insert date 180 days after date of publication in the* **Federal Register**]. 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. It is no longer necessary to send three copies of mailed 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–21583 Filed 8–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0431]

Draft Guidance for Food and Drug Administration Staff and Tobacco Retailers on Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." This guidance document is intended to describe FDA's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products, including the FD&C Act requirement that tobacco products may not be sold or distributed in violation of FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." When this guidance document is final, several provisions in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that relate to civil money penalties and no-tobacco-sale orders will become effective.

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 November 1, 2010.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. 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: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, *gerie.voss@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA Staff and tobacco retailers entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." On June 22, 2009, President Obama signed the Tobacco Control Act (Public Law 111–31) into law . The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Among its many provisions, the Tobacco Control Act authorizes FDA to impose civil money penalties for violations of FD&C Act requirements that relate to tobacco products (section 303(f)(9) of the FD&C Act (21 U.S.C. 333