TABLE 1.—PROPOSED DESIGN (4 X 5 + 2)

Information Type	Efficacy Level				
	Smallest Effect	Smaller Effect	Mid-Size Effect	Larger Effect	Largest Effect
Absolute Frequency	81% vs. 82%	61% vs. 82%	41% vs. 82%	21% vs. 82%	1% vs. 82%
Absolute Frequency + Qualitative Label	Fewer 81% vs. 82%	Fewer 61% vs. 82%	Fewer 41% vs. 82%	Fewer 21% vs. 82%	Fewer 1% vs. 82%
Absolute Difference + Qualitative Label	Fewer (1%)	Fewer (21%)	Fewer (41%)	Fewer (61%)	Fewer (81%)
Absolute Frequency + Absolute Difference + Qualitative Label	Fewer (1%) 81% vs. 82%	Fewer (21%) 61% vs. 82%	Fewer (41%) 41% vs. 82%	Fewer (61%) 21% vs. 82%	Fewer (81%) 1% vs. 82%

Note. Two other cells will be tested: (1) No information and (2) Qualitative label only (fewer). This design (22 cells) will also be used to test risk information (for a total of 44 cells). The specific numbers in the table are placeholders only. Qualitative label example: "fewer people taking drug X had disease/symptom Y."

The test product will be for the treatment of high prevalence medical condition and modeled on an actual drug used to treat that condition. Participants will be consumers who have been diagnosed with the medical condition of interest. They will be randomly assigned to read one ad version. After reading the ad, participants will answer a series of questions about the drug. We will test how the information type affects perceived efficacy, perceived risk, behavioral intention, and accurate understanding of the benefit and risk information.

Interviews are expected to last no more than 20 minutes. A total of 11,750 participants will be involved in the study. This will be a one-time (rather than annual) collection of information.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	750	1	750	20 minutes	250
Main Study	11,000	1	11,000	20 minutes	3,667
Total					3,917

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

Dated: August 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–21629 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–2009–E–0084]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PRISTIQ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim 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 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