INSPRA is 2,135 days. Of this time, 1,832 days occurred during the testing phase of the regulatory review period, while 303 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) became effective: November 24, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 24, 1996.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: November 29, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Inspra (NDA 21–437) was initially submitted on November 29, 2001.

3. The date the application was approved: September 27, 2002. FDA has verified the applicant's claim that NDA 21–437 was approved on September 27, 2002.

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 1,218 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**) written or electronic comments and ask for a redetermination by August 15, 2006. 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 13, 2006. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9412 Filed 6–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0022]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SYMLIN 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 written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug product 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 SYMLIN (pramlintide acetate). SYMLIN is given at mealtimes and is indicated for Type 1 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, and for Type 2 diabetes, as an adjunct treatment in patients who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a concurrent sulfonylurea agent and/or metformin. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SYMLIN (U.S. Patent No. 5,686,411) from Amylin Pharmaceuticals, 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 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SYMLIN represented the first permitted commercial marketing or use of the product. Shortly 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 SYMLIN is 4,620 days. Of this time, 3,060 days occurred during the testing phase of the regulatory review period, while 1,560 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*: July 24, 1992. The applicant claims July 29, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the

IND effective date was July 24, 1992, 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*: December 8, 2000. The applicant claims December 7, 2000, as the date the new drug application (NDA) for Symlin (NDA 21–332) was initially submitted. However, FDA records indicate that NDA 21–332 was submitted on December 8, 2000.

3. *The date the application was approved*: March 16, 2005. FDA has verified the applicant's claim that NDA 21–332 was approved on March 16, 2005.

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 1,586 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**) written or electronic comments and ask for a redetermination by August 15, 2006. 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 13, 2006. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9414 Filed 6–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Response to Solicitation on Organ Procurement and Transplantation Network (OPTN) Living Donor Guidelines

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

ACTION: Response to solicitation of comments.

SUMMARY: A notice was published in the **Federal Register** on January 23, 2006 (Vol. 71, No. 14, pages 3519–3520). The purpose of this notice was to solicit comments to assist HRSA in determining whether criteria developed by the Organ Procurement and Transplantation Network (OPTN) concerning organs procured from living donors, including those concerning the allocation of organs from living donors, should be given the same status, and be subject to the same enforcement actions, as other OPTN policies.

FOR FURTHER INFORMATION CONTACT: James F. Burdick, M.D., Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C–06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443–7577; fax (301) 594–6095; or e-mail: *jburdick@hrsa.gov*.

SUPPLEMENTARY INFORMATION: Congress has provided specific authority under sections 372 of the Public Health Service (PHS) Act, as amended, 42 U.S.C. 274 for the creation of a national OPTN, which is, among other things, to facilitate a donor and recipient matching system; establish membership criteria and medical criteria for allocating donated organs; and provide opportunities to members of the public to comment with respect to proposed criteria.

The OPTN Final Rule (42 CFR part 121) governs the operations of the OPTN and is intended to help achieve the most equitable and medically effective use of human organs that are donated in trust for transplantation. Under the final rule, the OPTN is to develop policies on a variety of issues, including ''[p]olicies for the equitable allocation of cadaveric organs [now referred to as deceased donor organs].'' 42 CFR 121.4(a)(1). Under the final rule, allocation policies developed by the OPTN under section 121.8 of the final rule will be considered enforceable when and if the Secretary approves the policies as such. Enforceable OPTN policies are subject to the sanctions described in section 121.10(c)(1) of the final rule. Non-enforceable OPTN policies may still be subject to lesser sanctions by the OPTN (*e.g.*, an OPTN member being designated a Member Not in Good Standing).

Although the authorizing statute does not distinguish between transplants using organs from living donors and those using organs from deceased donors, the final rule does not include a requirement that the OPTN develop policies concerning the equitable allocation of living donor organs. Until recently, OPTN policies have predominantly focused on issues related to organ donation and transplantation of deceased donor organs.

However, several widely publicized living donor deaths have caused the OPTN to implement new practices of reviewing and approving, on an advisory basis, the qualifications of living donor transplant programs. Additionally, the increased incidence of altruistic living donations has prompted the OPTN to consider policies that are patient-focused yet address the unique circumstances pertaining to the recovery and transplantation of living donor organs. Section 121.4(a)(6) of the final rule provides that the OPTN shall be responsible for developing policies on a variety of topics, including ''[p]olicies on such matters as the Secretary directs.'' In accordance with that authority, the Healthcare Systems Bureau directed the OPTN to develop allocation guidelines for organs from living donors and other policies necessary and appropriate to promote the safety and efficacy of living donor transplantation for the donor and recipient. It further advised the OPTN that all living donation policies (other than data reporting policies) should be considered as best practices or voluntary guidelines and not subject to regular OPTN sanctions (even those available with respect to violation of non-enforceable policies) until the public has had an opportunity to comment on the matter.

In the January 23, 2006, **Federal Register** notice, comments were requested to assist HRSA in determining whether OPTN living donor guidelines should be given the same status of other OPTN policies, *i.e.*, be treated as policies developed in accordance with 42 CFR 121.8, and be subject to the same enforcement actions. The Secretary explained that if he decided these questions in the affirmative, OPTN policies relating to living donors would be treated the same as other OPTN policies developed in accordance with section 121.8 of the final rule. In other words, OPTN policies concerning living