Application No.	Drug	Applicant
ANDA 84–015	Bleph–10 (sulfacetamide sodium ophthalmic ointment USP) Ophthalmic Ointment, 10%	Allergan, Inc.
ANDA 84–514	Dilor (dyphylline tablets USP), 200 mg	Savage Laboratories
ANDA 84–751	Dilor–400 (dyphylline tablets USP), 400 mg	Do.
ANDA 85–035	Diphenoxylate HCl and Atropine Sulfate Tablets USP, 2.5 mg and 0.025 mg	R & S Pharma, LLC, 8407 Austin Tracy Rd., Fountain Run, KY 42133
ANDA 85–961	Methocarbamol Tablets USP, 500 mg	Clonmel Healthcare Ltd., c/o STADA Pharmaceuticals, Inc., U.S. Agent, 5 Cedar Brook Dr., Cranbury, NJ 08512
ANDA 85–963	Methocarbomal Tablets USP, 750 mg	Do.
ANDA 86–899	Isoetharine HCl Inhalation Solution USP, 1%	Roxane Laboratories, Inc.
ANDA 87–450	Chlorthalidone Tablets USP, 50 mg	Clonmel Healthcare Ltd.
ANDA 87–451	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 87–500	Aminophylline Tablets USP, 100 mg	Roxane Laboratories, Inc.
ANDA 87–501	Aminophylline Tablets USP, 200 mg	Do.
ANDA 88–253	T-Phyl (theophylline) Extended-Release Tablets, 200 mg	The Purdue Frederick Co.

Therefore, under section 505(e), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective June 16, 2006.

Dated: May 23, 2006.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E6–9440 Filed 6–15–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0254]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for INSPRA 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 that 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–7), 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 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 INSPRA (eplerenone). INSPRA is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for INSPRA (U.S. Patent No. 4,559,332) from Novartis Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated June 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of INSPRA 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

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