Application No.	Drug	Applicant
NDA 20–144	TRANSDERM–NITRO (nitroglycerin), 0.1 mg/hour (hr), 0.2 mg/hr, 0.4 mg/hr, 0.6 mg/hr, 0.8 mg/hr	Novartis Pharmaceuticals Corp.
NDA 20–584	LODINE (etodolac) XL Tablets, 600 mg	Wyeth Pharmaceuticals, Inc.
NDA 21–110	RAPAMUNE (sirolimus) Tablets, 5 mg	Wyeth Pharmaceuticals, Inc.
NDA 50–477	NEBCIN (tobramycin sulfate) Injection, 10 mg/mL	Eli Lilly and Co.
NDA 50–519	NEBCIN (tobramycin sulfate) Injection, 1.2 grams/vial	Do.
ANDA 62–008	NEBCIN (tobramycin sulfate) Injection, 40 mg/mL	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. Approved ANDAs that refer to the NDAs and ANDA listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDA. Additional ANDAs for the products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 15, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9962 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0319]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BEXTRA 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 BEXTRA (valdecoxib). BEXTRA is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis and for the treatment of primary dysmenorrhea. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BEXTRA (U.S. Patent No. 5,633,272) from G.D. Searle, LLC, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BEXTRA 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 BEXTRA is 1,767 days. Of this time, 1,462 days occurred during the testing phase of the regulatory review period, while 305 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*: January 16, 1997. The applicant claims January 15, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the

IND effective date was January 16, 1997, 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*: January 16, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Bextra (NDA 21–341) was initially submitted on January 16, 2001.

3. *The date the application was approved*: November 16, 2001. FDA has verified the applicant's claim that NDA 21–341 was approved on November 16, 2001.

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 276 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 July 23, 2007. 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 November 19, 2007. 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 2, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–9957 Filed 5–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communication Messages—(OMB No. 0930–0196)—Extension

As the Federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addiction treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, the Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for development and dissemination of a wide range of education and information materials for both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

Activity	No. of respondents	Responses respondent	Hours per response	Total hours
Individual In-depth Interviews:				
General Public	400	1	.75	300
Service Providers	200	1	.75	150
Focus Group Interviews:				
General Public	3,000	1	1.5	4,500
Service Providers	1,500	1	1.5	2,250
Telephone Interviews:				
General Public	335	1	.08	27
Service Providers	165	1	.08	13
Self-Administered Questionnaires:				
General Public	2,680	1	.25	670
Service Providers	1,320	1	.25	330
Gatekeeper Reviews:				
General Public	1,200	1	.50	600
Service Providers	900	1	.50	450
Total	11,700	.....	.....	9,290

Written comments and recommendations concerning the proposed information collection should be sent by June 22, 2007 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.