applicant claims April 9, 2003, as the date the premarket approval application (PMA) for S8 OVER–THE–WIRE SYSTEM (PMA P030009) was initially submitted. However, FDA records indicate that PMA P030009 was submitted on April 10, 2003.

3. *The date the application was approved*: October 1, 2003. FDA has verified the applicant's claim that PMA P030009 was approved on October 1, 2003.

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 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 24, 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 August 22, 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: January 25, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–3127 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0355]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AMITIZA 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–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 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 AMITIZA (lubiprostone). AMITIZA is indicated for the treatment of chronic idiopathic constipation in the adult population. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AMITIZA (U.S. Patent No. 5,284,858) from Sucampo AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMITIZA 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 AMITIZA is 2,197 days. Of this time, 1,890 days occurred during the testing phase of the regulatory review period, while 307 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 28, 2000. The applicant claims January 29, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 28, 2000, 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*: March 31, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for AMITIZA (NDA 21–908) was initially submitted on March 31, 2005.

3. *The date the application was approved*: January 31, 2006. FDA has verified the applicant's claim that NDA 21–908 was approved on January 31, 2006.

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 1,251 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 April 24, 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 August 22, 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: February 3, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–3128 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0262]

Withdrawal of Approval of 128 Suitability Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 128 suitability petitions. This action is being taken in accordance with the Pediatric Research Equity Act of 2003 (PREA). Prior to PREA's enactment, FDA had approved these suitability petitions to permit abbreviated new drug applications (ANDAs) to be submitted for drugs that had a different active ingredient, dosage form, or route of administration than their reference listed drugs (RLDs). However, these approval decisions are being withdrawn because ANDAs were never submitted and PREA requires that all applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. This action is being taken without prejudice. Any of the suitability petitions may be resubmitted for action by the agency in accordance with current law.

DATES: This notice is effective March 26, 2007.

FOR FURTHER INFORMATION CONTACT: Cecelia M. Parise, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION: PREA (Public Law 108–155) was enacted on December 3, 2003. Among other things, section 2 of PREA requires that all drug applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. As a result, FDA is withdrawing its approval for 128 suitability petitions for which ANDAS were never submitted. The approval decisions, made prior to the enactment of PREA, would have permitted ANDAs to be submitted for certain drugs that have a different active ingredient, dosage form, or route of administration than their RLDs. No ANDAs were submitted for these drugs pursuant to these suitability petitions prior to April 1, 1999, and any such application submitted on or after April 1, 1999, would be required to contain the safety and effectiveness assessments required by PREA, unless waived or deferred. According to § 314.93(e)(1)(i) (21 CFR 314.93(e)(1)(i)), a suitability petition may not be approved if investigations must be conducted to show the safety and effectiveness of the drug product. In addition, according to § 314.93(f), FDA may withdraw approval of a suitability petition if it receives information demonstrating that the petition no longer satisfies the conditions of § 314.93(e). Under PREA, safety and effectiveness investigations in pediatric subpopulations would be required for the drug products proposed by these suitability petitions, unless the requirement is waived or deferred. Therefore, these suitability petitions no longer satisfy the regulatory requirements for approval. Pursuant to § 314.93(f), FDA is withdrawing approval of the 128 suitability petitions listed in the following table:

Petition No.	Drug	Petitioner
82N–0032/CP6	Chlorzoxazone 500 milligrams (mg)	Mikart, Inc.
84N–0116/CP1	Disopyramide Phosphate 200 mg or 300 mg	Biocraft Laboratories, Inc.
84P–0228/CP1	Acetaminophen 500 mg, Codeine Phosphate 30 mg or 60 mg	McNeil Pharmaceutical
85P–0067/CP1	Methyltestosterone 25 mg	Star Pharmaceuticals
85P–0074/CP1	Hydralazine Hydrochloride 25 mg/5 milliliters (mL)	Roxane Laboratories, Inc.
85P–0081/CP1	Flurazepam Hydrochloride 30 mg/mL	Do.
85P–0084/CP1	Vincristine Sulfate 2 mg	Bristol Laboratories