case, the Seventh Circuit held that the debarment statute is remedial rather than punitive in nature, but noted further that a law's general deterrent effect is consistent with a primarily remedial purpose (See id. at 494). The *Bae* court contrasted the general deterrent effect of the debarment statute with legislation intended to effect specific deterrence, noting that the latter ''aims to change a particular individual's behavior through negative reinforcement.'' This description of laws aimed at specific deterrence also characterizes Mr. Rodgers' interpretation of the debarment statute: His interpretation ties debarment to the continuing harm from the behavior of the particular individual facing debarment, rather than to a type of behavior that in general undermines drug regulation. In contrast, an interpretation of the term ''undermines'' to allow debarment for conduct with a general tendency to undermine the regulation of drugs is consistent with the statute's remedial goal of protecting the processes for the regulation of drugs by deterring all individuals from engaging in damaging conduct presently or in the future. See id.; see also *DiCola* v. *FDA*, 77 F. 3d 504, 506–508 (D.C. Cir. 1996) (discussing remedial purpose behind debarment statute).

Mr. Rodgers also argues that contrary to assertions included in the proposal to debar, the following statements are not included in the Information: (1) A detailed description of the LK–200 product (e.g., that it was a supernatant of white blood cell materials or that it meets the definition of a drug product); or (2) any claim that FDA was prevented from obtaining accurate and complete information necessary to regulate the drug process by Mr. Rodgers.

Mr. Rodgers' objection (that Mr. Rodgers' conduct described in the December 17, 2002, proposal to debar is not explicitly stated in the Information) does not raise a genuine and substantial issue of fact as to whether Mr. Rodgers was convicted of misdemeanors under Federal law or whether, as a matter of law, the convictions permit Mr. Rodgers' debarment. Mr. Rodgers does not deny the accuracy of the statements made in the proposal to debar, only that the descriptions of his conduct are not found in the Information.

Mr. Rodgers was convicted of three counts of violating the act, specifically section 301(p), (d), and (a), for owning and operating an unregistered facility for the manufacture of drugs; shipping an unapproved new drug in interstate commerce; and shipping an adulterated drug in interstate commerce (see, e.g., April 4, 2000, plea agreement letter from the U.S. Department of Justice U.S. Attorney, District of Massachusetts re: *United States* v. *Thomas M. Rodgers, Jr.*, whereby Mr. Rodgers expressly and unequivocally admits that Mr. Rodgers in fact committed the crimes charged in the Information, and is in fact guilty of those offenses; see also 68 FR 46197, at 46198, August 5, 2003, Thomas Ronald Theodore, Debarment Order, description of the LK–200 drug product). It is clear that there is no genuine and substantial issue of fact regarding whether Mr. Rodgers was convicted.

In accordance with § 12.24(b)(1), a hearing will only be granted if materials are submitted showing that there is a genuine and substantial issue of fact for resolution at a hearing. For the reasons set forth previously, FDA finds that Mr. Rodgers failed to identify any genuine and substantial issue of fact justifying a hearing. In addition, Mr. Rodgers' legal arguments do not create a basis for a hearing, and, in any event, are without merit. Accordingly, the Commissioner denies Mr. Rodgers' request for a hearing.

III. Findings and Order

Therefore, the Commissioner, under section 306(b)(2)(B)(i) of the act, and under the authority delegated to the Commissioner of Food and Drugs, finds that Mr. Thomas M. Rodgers, Jr., has been convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the act and that Mr. Rodgers' conduct which served as the basis for his conviction is the type of conduct that undermines the process for the regulation of drugs (21 U.S.C. 335a(b)(2)(B)(i)).

As a result of the foregoing findings, Mr. Thomas M. Rodgers, Jr. is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under sections 351 of the Public Health Service Act (42 U.S.C. 262). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Rodgers, in any capacity, during Mr. Rodgers' debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Rodgers, during his debarment, provides services in any capacity to a person with an approved or pending drug product application, including but not limited to, a biologics license application, Mr. Rodgers will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Rodgers during Mr. Rodgers' debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Rodgers for termination of debarment under section 306(d)(4) of the act should be identified with the Docket No. 2002N–0510 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies (21 CFR 10.20(a)). The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14967 Filed 7–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0410] (formerly Docket No. 03E–0410)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZUBRIN 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 animal 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: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product ZUBRIN (tepoxalin). ZUBRIN is indicated for the control of pain and inflammation associated with osteoarthritis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZUBRIN (U.S. Patent No. 4,826,868) from Johnson & Johnson, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of ZUBRIN 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 ZUBRIN is 2,347 days. Of this time, 1,887 days occurred during the testing phase of the regulatory review period, and 460 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) involving this animal drug product became effective:* October 28, 1996. The applicant claims October 29, 1996, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the date of FDA's letter assigning a number to the INAD was October 28, 1996, which is considered to be the effective date for the INAD.

2. *The date the application was initially submitted with respect to the animal drug product under section 512(b) of the act:* December 27, 2001. The applicant claims December 20, 2001, as the date the new animal drug application (NADA) for ZUBRIN (NADA 141–193) was initially submitted. However, a review of FDA records reveals NADA 141–193 was initially submitted on December 27, 2001.

3. *The date the application was approved:* March 31, 2003. FDA has verified the applicant's claim that NADA 141–193 was approved on March 31, 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 application for patent extension, this applicant seeks 1,405 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 comments and ask for a redetermination by September 26, 2005. 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 January 24, 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: June 29, 2005.

Jane A. Axelrad,

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

[FR Doc. 05–14921 Filed 7–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Class III Gaming Compacts taking effect.

SUMMARY: Notice is given that the Supplement to the Tribal-State Compact between the Chickasaw Nation and the State of Oklahoma is considered to have been approved and is in effect.

EFFECTIVE DATE: July 28, 2005.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Office of Indian Gaming Management, Office of the Deputy Assistant Secretary—Policy and Economic Development, Washington, DC 20240, (202) 219–4066.

SUPPLEMENTARY INFORMATION: Under Section 11(d)(7)(D) of the Indian Gaming Regulatory Act of 1988 (IGRA), Public Law 100–497, 25 U.S.C. 2710, the Secretary of the Interior must publish in the **Federal Register** notice of any Tribal-State compact that is approved, or considered to have been approved for the purpose of engaging in Class III gaming activities on Indian lands. The Acting Principal Deputy Assistant Secretary—Indian Affairs, Department of the Interior, through his delegated authority did not approve or disapprove this compact before the date that is 45 days after the date this compact was submitted. It could not be determined within the 45 day time frame to approve or disapprove this compact, whether the games listed, in the supplement to the compact, were class II or class III. Therefore, pursuant to 25 U.S.C. 2710(d)(7)(C), this supplement to the compact is considered to have been approved, but only to the extent that it is consistent with IGRA.

Dated: July 19, 2005.

Michael D. Olsen,

Acting Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 05–14966 Filed 7–27–05; 8:45 am]

BILLING CODE 4310–4N–P