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

Supplement Number One (1) to Tribal Gaming Compact Between the Chickasaw Nation and the State of Oklahoma

(1) This supplement is devised in accordance with the provisions of the Compact found at Part 3, paragraph 5.

(2) This supplement shall serve as certification that the Chickasaw Nation elects to include in the Compact the games in use as contained on the list included as Attachment A to the supplement, certified by the gaming commissioner of the Chickasaw Nation as being in use on February 24, 2005, and made a part hereto.

Submitted on May 2, 2005

For the Chickasaw Nation:

Bill Anoatubby

Bill Anoatubby, Governor