FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2004–SEPTEMBER 30, 2005—Continued

[Fiscal year 2005]

State	Federal medical assistance percentages	Enhanced Federal medical assistance percentages
Northern Mariana Islands*	50.00	65.00
Ohio	59.68	71.78
Oklahoma	70.18	79.13
Oregon	61.12	72.78
Pennsylvania	53.84	67.69
Puerto Rico*	50.00	65.00
Rhode Island	55.38	68.77
South Carolina	69.89	78.92
South Dakota	66.03	76.22
Tennessee	64.81	75.37
Texas	60.87	72.61
Utah	72.14	80.50
Vermont	60.11	72.08
Virgin Islands*	50.00	65.00
Virginia	50.00	65.00
Washington	50.00	65.00
West Virginia	74.65	82.26
Wisconsin	58.32	70.82
Wyoming	57.90	70.53

*For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI will be 75 per centum.
**The values for Alaska and the District of Columbia in the table were set for the state plan under titles XIX and XXI and for capitation payments and DSH allotments under those titles. For other purposes, including programs remaining in Title IV of the Act, the percentage for Alaska is 53.23 and for D.C is 50.00.

[FR Doc. 03–30095 Filed 11–28–03; 12:19 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0106]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; and Electronic Submission Using FDA Forms 3503 and 3504

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; and Electronic Submission Using FDA Forms 3503 and 3504'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 2003 (68 FR 44342), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0016. The approval expires on November 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–30029 Filed 12–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0261]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for STRATTERA 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: Claudia V. 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug 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 STRATTERA (atomoxetine hydrochloride). STRATTERA is indicated for the treatment of attention-deficit/hyperactivity disorder. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for STRATTERA (U.S. Patent No. 5,658,590,) from Eli Lilly & Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 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 STRATTERA 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 STRATTERA is 7,718 days. Of this time, 7,307 days occurred during the testing phase of the regulatory review period, while 411 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*: October 11, 1981. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 11, 1981.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: October 12, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for STRATTERA (NDA 21–411) was initially submitted on October 12, 2001.

3. *The date the application was approved*: November 26, 2002. FDA has verified the applicant's claim that NDA 21–411 was approved on November 26, 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 685 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 comments and ask for a redetermination by February 2, 2004. 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 June 1, 2004. 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: October 30, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–30028 Filed 12–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–03–7000]

Memorandum of Understanding Between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and Agricultural Marketing Service, United States Department of Agriculture. The purpose of the MOU is to ensure that sponsors of new antimicrobial animal drugs have access to an effective means for evaluating the effects of their drugs on current Food Safety and Inspection Service detection tests.

DATES: The agreement became effective January 23, 2003.

FOR FURTHER INFORMATION CONTACT: Valerie Reeves, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6973.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108 (c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: November 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S