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 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9213 Filed 6–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0043]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TYGACIL 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 TYGACIL (tigecycline). TYGACIL is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed in this paragraph for patients 18 years of age and older: (1) Complicated skin and skin structure infections caused by *Escherichia coli* (*E. coli*), *Enterococcus* (*Entero.*) *faecalis* (vancomycin-susceptible isolates only), *Staphlococcus* (*Staph.*) *aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus* (*Strept.*) *agalactiae*, *Strept. anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Strept. Pyogenes*, and *Bacteroides* (*B.*) *fragilis*, and (2) Complicated intra-abdominal infections caused by *Citrobacter freundii*, *Enterobacter cloacae*, *E. coli*, *Klebsiella* (*K.*) *oxytoca*, *K. pneumoniae*, *Entero. faecalis* (vancomycin-suspectible isolates only), *Staph. aureus* (methicillin-susceptible isolates only), *Strept. anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *B. fragilis*, *B. thetaiotaomicron*, *B. uniformis*, *B. vulgatus*, *Clostridium perfringens*, and *Peptostreptococcus micros*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for TYGACIL (U.S. Patent No. 5,529,990) from Wyeth Holdings Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 24, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of TYGACIL 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 TYGACIL is 2,487 days. Of this time, 2,304 days occurred during the testing phase of the regulatory review period, while 183 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*: August 26, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 26, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 15, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for Tygacil (NDA 21–821) was initially submitted on December 15, 2004.

3. *The date the application was approved*: June 15, 2005. FDA has verified the applicant's claim that NDA 21–821 was approved on June 15, 2005.

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 1,335 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 August 14, 2006. 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 December 11, 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: May 17, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–9214 Filed 6–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on this project or to obtain a copy of the data collection plans and instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Advanced Education Nursing Traineeship and Nurse Anesthetist Traineeship Forms

The Health Resources and Services Administration (HRSA) developed the Advanced Education Nursing Traineeship (AENT) and Nurse Anesthetist Traineeship (NAT) Forms for the Guidance Application for the Traineeship Programs. The AENT/NAT Traineeship forms are used annually by new applicants that are applying for AENT and NAT funding. The AENT and NAT programs provide training grants to educational institutions to increase the numbers of advanced education nurses. Award amounts are based on enrollment, traineeship support, graduate data and two funding preferences to institutions which meet the criteria for the preference.

The AENT/NAT Traineeship forms include information on program participants such as the number of enrollees, number of graduates and the types of programs they are enrolling into and/or graduating from. These forms will be available electronically through Grants.gov. AENT and NAT applicants will have a single access point to submit their grant applications and AENT/NAT Traineeship forms.

The system will be designed so that the data from the prior year's submission will be pre-populated. This will significantly reduce the burden to AENT and NAT applicants. They will need only edit those sections that have changed. The electronic system will conduct automated checks on data validity, data consistency and application completeness. This facilitates application review and eliminates much of the previously required data cleansing. Finally, data from this system will be used in the award determination and validation process. Additionally, the data will be used to ensure programmatic compliance, report to Congress and policymakers on the program accomplishments, formulate, and justify future budgets for these activities submitted to the Office of Management and Budget and Congress.

The estimated average annual burden per year is as follows:

Type of respondent	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours
AENT	350	1	1	350
NAT	80	1	1	80
Total	430	.....	.....	430

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of notice.

Dated: June 6, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–9199 Filed 6–12–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c) (2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the Heath Resources and Services Administration Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be