TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Tool	3,300	1	3,300	.05	165
Stage 1: Part A—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Stage 1: Part B—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Stage 2—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Total	.....	.....	.....	.....	705

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

This was based on similar types of FDA studies conducted in the past. FDA has conducted both focus group studies and label comprehension studies, where similar participant activities, such as reading the labeling, taking the REALM test, signing the informed consent, and answering questions on a self-administered questionnaire took place. In order to achieve the 1,200 participants for the condom label comprehension study, FDA estimates screening 3,300 to achieve 1,200 interviews.

Dated: February 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2716 Filed 2–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0355]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 19, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Exception From General Requirements for Informed Consent—(OMB Control Number 0910–0586)—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule (hereinafter referred to as the June 7, 2006, interim final rule) to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency took this action because it is concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

FDA requested public comment on the information collection requirements in the June 7, 2006, interim final rule.

The collection of information requirements for the June 7, 2006, interim final rule were approved under the emergency processing provisions of the Paperwork Reduction Act (PRA), and assigned OMB control 0910–0586. With this approval, OMB informed the agency that the preamble and solicitation of public comment by the June 7, 2006, interim final rule would serve as a 60-day notice for the 3 year extension of this collection of information. In addition, OMB also requested that FDA, in submitting its extension request, summarize comments received in response to the 60-day notice, describe how the agency will address substantive issues raised by the commenters, and provide an update on the status of the final rule. FDA is responding to OMB's requests below:

FDA received 10 comments on the interim final rule, three of which related to the information collection requirements. The other comments on the rule will be addressed in the preamble to the final rule. FDA expects to publish the final rule in 2009.

One comment suggested that the requirement that a laboratory certify to an institutional review board (IRB) that the testing was done in a life-threatening situation and that it was not feasible to obtain consent serves no purpose, since these issues have already been pre-determined by FDA and provide the basis for exemption. FDA disagrees. The certification requirement ensures that the laboratory documents for the IRB that it is complying with the requirements of the regulation. The comment also stated that the concurrence of an independent physician, which will occur post-

testing, adds no value to the certification. FDA also disagrees with this point: the information is necessary because it provides confirmation from an independent source that the regulations are being followed. This provision is found in other FDA regulations and is an important additional protection to the subjects in these trials. Lastly, the comment stated that providing the subject with consent information is of no value because at that time the subject can not choose whether to have the specimen tested since the test has already been performed. According to the comment, sending the subject a copy of the notice to the IRB should be sufficient. While the comment correctly states that subjects can not give informed consent after the test has been performed, providing subjects with this information demonstrates respect for the individual (one of the core principles in the Belmont Report and an important component of human subject protection) by fully informing them of the circumstances of the trial. It would not be appropriate to send the subject the information provided to the IRB because the type of information the IRB usually receives would not fully inform the subject about the trial; the IRB document is typically written in technical language that is likely to be less understandable to subjects.

Another comment requested that § 50.32(e)(4) explicitly require investigators to notify the jurisdictional public health authority upon suspicion of need for testing for a chemical, biological, radiological, or nuclear agent with the investigational device; and further that the language should reinforce that investigators must provide test results to the jurisdictional public health authority in accordance with State and/or Federal law. This comment falls out of the scope of the questions posed in the **Federal Register** notice and this type of reporting to public health authorities is beyond FDA's purview.

The last comment encouraged FDA to consider increasing the length of time in which the written certification for the exception is required to be submitted, with the goal of easing the reporting burden. The certification is required to be submitted within 5 working days of the use of the investigational device. FDA believes that the 5-day reporting period is important because it helps ensure that IRBs will receive timely notice of instances in which this rule is used. In addition, the 5-day reporting period appears in other FDA human subject protection regulations that address other exceptions to the general requirement of obtaining informed consent and the agency believes that it is important to maintain consistency within its regulations wherever possible.

The likely respondents for this collection of information are clinical laboratories and physicians.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
50.23(e)(1) and (e)(2)	150	3	450	2	900
50.23(e)(4)	150	3	450	1	450
Total Hours					1,350

[1] There are no capital costs or operating and maintenance costs associated with this collection of Information.

FDA is adding § 50.23(e)(1) (21 CFR 50.23(e)(1)) to provide an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception will apply to those situations in which the in vitro investigational diagnostic device is used to prepare for and respond to a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device; (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative; and (3) no satisfactory alternative device is available. Under the June 7, 2006, interim final rule these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the IRB within 5 working days of the use of the device.

From its knowledge of the industry, FDA estimates that there are approximately 150 laboratories that could perform this type of testing. FDA estimates that in the United States each year there are approximately 450 naturally occurring cases of diseases or conditions that are identified in CDC's list of category 'A' biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to prepare each certification.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under the June 7, 2006, interim final rule, the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare this information and submit it to the health care provider and, where appropriate, to public health authorities.

Dated: February 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2794 Filed 2–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0236]

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. faecaliss* (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. 5,494,903) 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 June 14, 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 April 17, 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 15, 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