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 GANIRELIX ACETATE INJECTION (ganirelix acetate). GANIRELIX ACETATE INJECTION is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GANIRELIX ACETATE INJECTION (U.S. Patent No. 4,801,577) from Syntex, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GANIRELIX ACETATE INJECTION 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 GANIRELIX ACETATE INJECTION is 3,558 days. Of this time, 3,376 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: November 2, 1989. The applicant claims October 3, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 2, 1989, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: January 29, 1999. The applicant claims January 28, 1999, as the date the new drug application (NDA) for GANIRELIX ACETATE INJECTION (NDA 21–057) was initially submitted. However, FDA records indicate that NDA 21–057 was submitted on January 29, 1999.

3. *The date the application was approved*: July 29, 1999. FDA has verified the applicant's claim that NDA 21–057 was approved on July 29, 1999.

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 5 years 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 January 3, 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 May 2, 2005. 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 (see **ADDRESSES**). 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 15, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–24378 Filed 11–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2004–19483]

Review and Approval of Classification Societies

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy; request for comments.

SUMMARY: This notice contains procedures the Coast Guard will use to review classification societies seeking Coast Guard approval to perform certain functions for vessels. Under the 2004 Coast Guard and Maritime Transportation Authorization Act, after January 1, 2005, classification societies may not perform those certain functions for vessels unless they are either approved by the Coast Guard or are full members of the International Association of Classification Societies. Class societies seeking Coast Guard approval should submit a package in accordance with the procedures in this notice. The Coast Guard also seeks public comment on the procedures described herein for reviewing and approving classification societies.

DATES: This notice of policy is effective November 2, 2004. Comments and related material must reach the Docket Management Facility on or before January 3, 2005.

ADDRESSES:

Application Process

Classification societies may request review and approval by writing to Commandant (G–MSE), 2100 Second Street, SW., Washington, DC 20593–0001.

Comment Submissions

You may submit comments identified by Coast Guard docket number USCG–2004–19483 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Web site: http://dms.dot.gov.*

(2) *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(3) *Fax:* (202) 493–2251.

(4) *Delivery:* Room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(5) *Federal eRulemaking Portal: http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this notice of policy, contact Mr. William Peters, Office of Design and Engineering Standards, (G–MSE–2), Coast Guard, telephone 202–267–2988, e-mail: *wpeters@comdt.uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

The criteria for classification society approval is based, in part, on the International Maritime Organization (IMO) Resolution A.739(18), ''Guidelines for the Authorization of Organizations Acting on Behalf of the Administration.'' Resolution A.739(18) establishes minimum requirements for Recognized Organizations (ROs) to act on the behalf of Administrations in the surveys and certification and determination of vessel tonnages as required by the applicable international conventions. After review and consideration, the Coast Guard deems Resolution A.739(18) to provide a sound and internationally recognized standard from which to base the review and approval program required by 46 U.S.C. 3316(c).

Classification societies often act as ROs because of the similarity in the technical and survey work these organizations perform. To be authorized under the resolution, an RO must satisfy the Administration that their business practices are aligned with the standards of Resolution A.739(18). The RO is required to publish and systematically maintain rules, be professionally staffed with strategically placed resources for geographic coverage, maintain a high level of professional ethics, be competent, provide timely and quality services, and maintain an internal quality system no less effective than ISO 9000 series certification.

In addition, the statute outlines additional requirements for approval as follows:

(1) Vessels surveyed by the classification society must have an adequate safety record;

(2) The classification society must have an adequate program to develop and implement safety standards for vessels it surveys;

(3) The classification society must have an adequate program to make their safety records available to the Secretary in an electronic format;

(4) The classification society must have a program to make the safety records of a vessel available to other classification societies (for the purpose of a specific vessel survey); and

(5) The classification society must have a program to request records from other classification societies that previously surveyed the vessel.

As further evidence of the adequacy of the safety record of item (2) above, the Coast Guard also requires that a classification society is an RO for at least one sovereign nation that is signatory to the International Safety of Life at Sea (SOLAS), MARPOL 73/78, the International Convention on Load Lines (ICLL), 1966, and the Protocol of 1988 relating to the ICLL, 1966.

Discussion of Notice of Policy

This notice of policy describes the approval process by which classification societies may comply with 46 U.S.C. 3316(c). This process includes approval criteria, review and approval procedures, and application procedures to assist classification societies to comply with this statute. This process differs from the requirements of 46 U.S.C. 3316(b) that establish criteria by which certain statutory functions may be delegated to the American Bureau of Shipping or other recognized classification societies.

Candidate Application Submittals

For the purposes of 46 U.S.C. 3316(c), a classification society desiring an approval may apply in writing to Commandant (G–MSE), 2100 Second Street, SW., Washington, DC 20593–0001. An application package (written in English) must:

(1) Indicate the type of work the classification society wishes to perform on vessels in the United States;

(2) Provide appropriate documentation proving that the classification society has applied for and received approval as an RO from at least one Administration that is signatory to SOLAS, MARPOL 73/78, Load Lines, 1966, and the Protocol of 1988 relating to Load Lines, 1966, under the provisions of IMO Resolution A.739(18);

(3) Demonstrate that the classification society operates as an RO on behalf of at least one Administration under a formal written agreement that includes all of the elements set out in Resolution A.739(18), Appendix 2;

(4) Demonstrate that the classification society maintains all of the minimum standards for ROs as set forth in Resolution A.739(18), Appendix 1;

(5) Demonstrate that the classification society is subject to a satisfactory system of verification and monitoring by at least one Administration, as set forth in the Annex to IMO Resolution A.739(18);

(6) Provide a list of the vessels surveyed by the classification society including vessel names, flags, and IMO numbers;

(7) Describe a system in which the classification society makes its safety records and those of persons acting on behalf of the classification society available to the Coast Guard in electronic format;

(8) Describe a system in which the classification society provides its safety records and those of persons acting on behalf of the classification society to another classification society that requests those records for the purpose of conducting surveys of vessels; and

(9) Describe a system in which the classification society or those persons acting on its behalf are capable of requesting the safety records of a vessel to be surveyed from any other classification society that previously surveyed a vessel.

On or after January 1, 2005, a classification society (including an employee or agent of that society) may not review, examine, survey, or certify the construction, repair, or alteration of a vessel in the United States unless it is a full member of the International Association of Classification Societies (IACS) or is approved by the Coast Guard.

Classification societies authorized to perform work on behalf of the United States under the provisions of 46 U.S.C. 3316(b) and all full members of IACS are approved to perform functions otherwise prohibited by 46 U.S.C. 3316(c).

Comments and Viewing Documents Referenced in This Notice

If you wish to submit comments regarding this notice, please send them to the Docket Management Facility at the address under **ADDRESSES**. All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this rulemaking (USCG–2004–19483), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We will review this policy and may amend it in view of comments received.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov*.

Dated: October 28, 2004.

Howard L. Hime,

Acting Director of Standards, Marine Safety, Security and Environmental Protection, U.S. Coast Guard.

[FR Doc. 04–24453 Filed 10–29–04; 11:40 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4910–N–24]

Notice of Proposed Information Collection for Public Comment; HOPE VI Programs: Data Collection

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* January 3, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Aneita Waites, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410–5000.

FOR FURTHER INFORMATION CONTACT: Aneita Waites, (202) 708–0713, extension 4114, for copies of the proposed forms and other available documents. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: HOPE VI Programs: Data Collection.

OMB Control Number: 2577–0208.

Description Of The Need For The Information And Proposed Use: Section 24 of the U.S. Housing Act of 1937, as added by section 535 of the Quality Housing and Work Responsibility Act of 1998 (Pub. L. 105–276, 112 Stat. 2461, approved October 21, 1998) and the HOPE VI Program Reauthorization and Small Community Mainstreet Rejuvenation and Housing Act of 2003 (Pub. L. 108–186, 117 Stat. 2685, approved December 16, 2003) establishes the HOPE VI program for the purpose of making assistance available on a competitive basis to public housing agencies (PHAs) in improving the living environment for public housing residents of severely distressed public housing projects through the demolition, rehabilitation, reconfiguration, or replacement of severely distressed public housing projects (or portions thereof); in revitalizing areas in which public housing sites are located, and contributing to the improvement of the surrounding community; in providing housing that avoids or decreases the concentration of very low-income families; and in building sustainable communities. In addition, the HOPE VI Program Reauthorization and Small Community Mainstreet Rejuvenation and Housing Act of 2003 adds to the HOPE VI program the purpose of making assistance available on a competitive basis to small units of local government to develop affordable housing as part of Main Street rejuvenation projects.

Agency Form Number: HUD–52774, HUD–52780, HUD–52785, HUD–52787, HUD–52789, HUD–52790, HUD–52797, HUD–52799, HUD–52800, HUD–52825–A, HUD–52860–A, HUD–52861, HUD–53001, and HUD–53001–A.

Members Of Affected Public: Public Housing Agencies, Units of local government with populations of less than 50,000.

Estimation of the total number of hours needed to prepare the information collection including number of respondents: