

IND effective date was January 16, 1997, 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(b) of the act:* January 16, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Bextra (NDA 21-341) was initially submitted on January 16, 2001.

3. *The date the application was approved:* November 16, 2001. FDA has verified the applicant's claim that NDA 21-341 was approved on November 16, 2001.

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 276 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 July 23, 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 November 19, 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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 2, 2007.

**Jane A. Axelrad,**

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

[FR Doc. E7-9957 Filed 5-22-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Pretesting of Substance Abuse Prevention and Treatment and Mental Health Services Communication Messages—(OMB No. 0930-0196)—Extension**

As the Federal agency responsible for developing and disseminating authoritative knowledge about substance abuse prevention, addiction treatment, and mental health services and for mobilizing consumer support and increasing public understanding to overcome the stigma attached to addiction and mental illness, the Substance Abuse and Mental Health Services Administration (SAMHSA) is responsible for development and dissemination of a wide range of education and information materials for both the general public and the professional communities. This submission is for generic approval and will provide for formative and qualitative evaluation activities to (1) assess audience knowledge, attitudes, behavior and other characteristics for the planning and development of messages, communication strategies and public information programs; and (2) test these messages, strategies and program components in developmental form to assess audience comprehension, reactions and perceptions. Information obtained from testing can then be used to improve materials and strategies while revisions are still affordable and possible. The annual burden associated with these activities is summarized below.

Activity	No. of respondents	Responses respondent	Hours per response	Total hours
Individual In-depth Interviews:				
General Public .....	400	1	.75	300
Service Providers .....	200	1	.75	150
Focus Group Interviews:				
General Public .....	3,000	1	1.5	4,500
Service Providers .....	1,500	1	1.5	2,250
Telephone Interviews:				
General Public .....	335	1	.08	27
Service Providers .....	165	1	.08	13
Self-Administered Questionnaires:				
General Public .....	2,680	1	.25	670
Service Providers .....	1,320	1	.25	330
Gatekeeper Reviews:				
General Public .....	1,200	1	.50	600
Service Providers .....	900	1	.50	450
<b>Total .....</b>	<b>11,700</b>	<b>.....</b>	<b>.....</b>	<b>9,290</b>

Written comments and recommendations concerning the proposed information collection should be sent by June 22, 2007 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management

and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service,

respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: May 7, 2007.  
**Elaine Parry,**  
*Acting Director, Office of Program Services.*  
 [FR Doc. E7-9900 Filed 5-22-07; 8:45 am]  
**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5117-N-44]

**Notice of Submission of Proposed Information Collection to OMB; Early Doctoral Student Research Grant Program**

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been 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.

Doctoral students will receive grants to complete their dissertations related to HUD subjects.

**DATES:** *Comments Due Date:* June 22, 2007.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2528-0216) and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Lillian\_L\_Deitzer@HUD.gov* or telephone (202) 708-2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Deitzer or from HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm*.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting 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:* Early Doctoral Student Research Grant Program.

*OMB Approval Number:* 2528-0216.

*Form Numbers:* SF-424, SF-424 Supplement, HUD-424CB, SFLLL, HUD-27300, HUD-2880, HUD-2944A, HUD-96010, HUD-96011.

*Description of the Need for the Information and Its Proposed Use:* Doctoral students will receive grants to complete their dissertations related to HUD subjects.

*Frequency of Submission:* On occasion, Semi-annually, Other Final Report.

	Number of respondents	Annual responses	x	Hours per response	=	Burden hours
Reporting Burden .....	80	1.56		21.68		2710

*Total Estimated Burden Hours:* 2,710.  
*Status:* Extension of a current collection.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: May 18, 2007.

**Lillian L. Deitzer,**  
*Departmental Paperwork Reduction Act Officer, Office of the Chief Information Officer.*  
 [FR Doc. E7-9953 Filed 5-22-07; 8:45 am]  
**BILLING CODE 4210-67-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5117-N-43]

**Notice of Submission of Proposed Information Collection to OMB; Mortgage Insurance Termination; Application for Premium Refund or Distributive Share Payment**

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below has been 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.

The Mortgage Insurance Termination Information is used by FHA-approved lenders to terminate FHA insurance to comply with HUD requirements. The Application for Premium Refund or Distributive Share Payment is used by homeowners to apply for the unearned portion of the mortgage insurance premium or a distributive share payment.

**DATES:** *Comments Due Date:* June 22, 2007.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval Number (2502-0414) and

should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Lillian Deitzer, Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Lillian\_L\_Deitzer@HUD.gov* or telephone (202) 708-2374. This is not a toll-free number. Copies of available documents submitted to OMB may be obtained from Ms. Deitzer or from HUD's Web site at *http://www5.hud.gov:63001/po/i/icbts/collectionsearch.cfm*.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that the Department of Housing and Urban Development has submitted to OMB a request for approval of the information collection described below. This notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of