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 Commissioner 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 NISOCOR (nisoldipine). NISOCOR is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NISOCOR (U.S. Patent No. 4,154,839) from Bayer AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 22, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NISOCOR 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 NISOCOR is 4,965 days. Of this time, 4,292 days occurred during the testing phase of the regulatory review period, while 673 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 (21 U.S.C. 355(i)) became effective*: July 2, 1981. The applicant claims May 22, 1989, as the date the investigational new drug application (IND) became effective, based on IND 33,244. However, FDA records indicate that the effective date for the first IND submitted for NISOCOR, IND 18,813, was July 2, 1981, 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 Federal Food, Drug, and Cosmetic Act*: April 1, 1993. The applicant claims March 31, 1993, as the date the new drug application (NDA) for NISOCOR (NDA 20–356) was initially submitted. However, FDA records indicate that NDA 20–356 was submitted on April 1, 1993.

3. *The date the application was approved*: February 2, 1995. FDA has verified the applicant's claim that NDA 20–356 was approved on February 2, 1995.

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 1,377 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 29, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 29, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affiars.

[FR Doc. 95–18687 Filed 7–28–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda Purpose: To review and evaluate grant applications
Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: July 30–August 1, 1995
Time: 7 p.m.
Place: Galleria Park Hotel, 191 Sutter Street, San Francisco, CA 94104
Contact Person: Jean G. Noronha, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: August 2–August 4, 1995
Time: 7 p.m.
Place: Madison Hotel, 1177 15th Street NW., Washington, DC 20036
Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–6470.

Committee Name: National Institute of Mental Health Special Emphasis Panel
Date: August 16, 1995
Time: 8:30 a.m.
Place: Loews, 51st and Lexington, New York, NY
Contact Person: Angela L. Redlingshafer, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, telephone: 301, 443–1367.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen days prior to the meetings due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Numbers 93.242, Small Business Innovation Research; 93.242, Mental Health

Research Grants; 93.121, Scientist Development Awards; 93.282, Mental Health Research Service Awards for Research Training)

Dated: July 25, 1995.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 95–18853 Filed 7–28–95; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. FR–3911–N–02]

Mortgagee Review Board Administrative Actions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In compliance with Section 202(c) of the National Housing Act, notice is hereby given of the cause and description of administrative actions taken by HUD's Mortgagee Review Board against HUD-approved mortgagees.

FOR FURTHER INFORMATION CONTACT: William Heyman, Director, Office of Lender Activities and Land Sales Registration, 451 Seventh Street, S.W., Washington, D.C. 20410, telephone (202) 708–1515. The Telecommunication Device for the Deaf (TDD) number is (202) 708–4594. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: Section 202(c)(5) of the National Housing Act (added by Section 142 of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101–235), approved December 15, 1989, requires that HUD ''publish in the **Federal Register** a description of and the cause for administrative action against a HUD-approved mortgagee'' by the Department's Mortgagee Review Board. In compliance with the requirements of Section 202(c)(5), notice is hereby given of administrative actions that have been taken by the Mortgagee Review Board from April 1, 1995 through June 30, 1995.

1. Community Lending Corporation, College Park, Maryland

Action: Probation and proposed civil money penalty in the amount of $5,000.

Cause: Failure by the company to remit to the Department mortgage insurance premiums collected from borrowers in connection with five HUD-FHA insured mortgage transactions; and failure to timely submit loans to HUD-FHA for mortgage insurance endorsement.

2. World Wide Credit Corporation, San Diego, California

Action: Proposed Settlement Agreement of a civil money penalty in the amount of $1,500; indemnification for any claim losses in connection with 10 improperly originated Title I loans; and implementation of a Quality Control Plan.

Cause: A HUD monitoring review that disclosed violations of HUD-FHA Title I program requirements that included: failure to document borrower's source of funds required for loan fees and closing costs; advising borrowers that loan fees may be deducted from loan proceeds; improperly advising borrowers to obtain gift letters; and omitting the loan disbursement date on the Note.

3. Greystone Servicing Corporation, Inc., New York, New York

Action: Settlement Agreement that includes a payment to the Department in the amount of $228,000 and assurance by the company of compliance with the requirements of the Government National Mortgage Association (GNMA).

Cause: Violation of GNMA requirements resulting from the improper termination of 57 GNMA mortgage-backed securities pools.

4. Whitehall Funding, Inc., Davenport, Iowa

Action: Settlement Agreement that includes a payment to the Department in the amount of $75,000 and assurance by the company of compliance with the requirements of the Government National Mortgage Association (GNMA).

Cause: Violation of GNMA requirements resulting from the improper termination of 13 GNMA mortgage-backed securities pools.

5. Washington Credit Union, Lynwood, Washington

Action: Probation and proposed civil money penalty in the amount of $10,000.

Cause: A HUD monitoring review that disclosed violations of HUD-FHA Title I property improvement loan program requirements that included: failure to comply with HUD-FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to comply with dealer approval requirements; failure to report to HUD-FHA borrowers' uncompleted property improvements; failure to resolve a borrower complaint against a dealer; failure to verify a borrower's source of funds for the required initial payment; and inaccurate completion certificates.

6. Carl I Brown & Company, Kansas City, Missouri

Action: Proposed Settlement Agreement that includes payment to the Department of $75,000; payment of a civil money penalty in the amount of $30,000; and corrective action by the company to assure compliance with HUD-FHA requirements.

Cause: Review by HUD's contractor of the company's single family mortgage insurance claims submissions and loan servicing procedures that disclosed violations of HUD-FHA requirements. The violations included: overpayment by HUD of expenses paid; payment for preservation and protection work not performed; overpayment for tax refunds; improperly prepared claims submissions; inadequate quality control; improper dispositions of mortgagor escrow surpluses; and inadequate servicing of defaulted loans.

7. PNC Mortgage Corp. of America, Vernon Hills, Illinois

Action: Proposed Settlement Agreement that includes payment to the Department in the amount of $84,375, and if determined to be appropriate, reimbursement for marketing losses resulting from untimely submitted insurance claims.

Cause: Review by HUD's contractor of the company's single family mortgage insurance claims submissions citing violations of HUD-FHA requirements that included: untimely submission of insurance claims; and incorrect dates on claim forms.

8. Charter Mortgage Corporation, Fort Lauderdale, Florida

Action: Probation

Cause: A HUD monitoring review that disclosed violations of HUD-FHA requirements that included: failure to comply with HUD-FHA reporting requirements under the Home Mortgage Disclosure Act (HMDA); failure to maintain an adequate Quality Control Plan; permitting improperly secured secondary financing to close HUD-FHA insured mortgages; failure to remit to HUD-FHA Up-Front Mortgage Insurance Premiums (UFMIPs) and late charges; submission of erroneous HUD–1 Settlement Statements; and failure to retain complete loan origination files.