

approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Alunex®. Alunex® is indicated as an aid for ultrasound contrast enhancement of ventricular chambers and improvement of endocardial border definition in patients with suboptimal echoes undergoing ventricular function and regional wall motion studies. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Alunex® (U.S. Patent No. 4,844,882) from Molecular Biosystems, Inc., 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 19, 1994, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Alunex® represented the first commercial marketing 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 Alunex® is 2,397 days. Of this time, 975 days occurred during the testing phase of the regulatory review period, while 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* January 14, 1988. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) for human tests to begin became effective on August 18, 1987. However, FDA records indicate that IDE was conditionally approved on January 14, 1988, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*

360e): September 14, 1990. The applicant claims September 11, 1990, as the date the premarket approval application (PMA) for Alunex® (PMA P900059) was initially submitted. However, FDA records indicate that PMA P900059 was submitted on September 14, 1990.

3. *The date the application was approved:* August 5, 1994. FDA has verified the applicant's claim that PMA P900059 was approved on August 5, 1994.

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 763 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 1, 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 August 29, 1995, 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: February 24, 1995.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 95-5183 Filed 3-1-95; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

Division of Research Grants; 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 Division

of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: March 2, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 309, Telephone Conference.

Contact Person: Dr. Jane Hu, Scientific Review Administrator, 5333 Westbard Ave., Room 309, Bethesda, MD 20892, (301) 594-7269.

Name of SEP: Behavioral and Neurosciences.

Date: March 20, 1995.

Time: 1:30 p.m.

Place: NIH, Westwood Building, Room 303, Telephone Conference.

Contact Person: Dr. Teresa Levitin, Scientific Review Administrator, 5333 Westbard Ave., Room 303, Bethesda, MD 20892, (301) 594-7141.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 20, 1995.

Time: 12:00 noon.

Place: NIH, Westwood Building, Room 226, Telephone Conference.

Contact Person: Dr. Gerald Liddel, Scientific Review Admin., 5333 Westbard Ave., Room 226, Bethesda, MD 20892, (301) 594-7167.

Name of SEP: Biological and Physiological Sciences.

Date: March 23, 1995.

Time: 1:00 p.m.

Place: NIH, Westwood Building, Room 233A, Telephone Conference.

Contact Person: Dr. Robert Su, Scientific Review Administrator, 5333 Westbard Ave., Room 233A, Bethesda, MD 20892, (301) 594-7320.

Name of SEP: Microbiological and Immunological Sciences.

Date: March 31, 1995.

Time: 10:00 a.m.

Place: NIH, Westwood Building, Room 226, Telephone Conference.

Contact Person: Dr. Gerald Liddel, Scientific Review Admin., 5333 Westbard Ave., Room 226, Bethesda, MD 20892, (301) 594-7167.

The meetings will be closed in accordance with the provisions set forth in secs. 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 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 24, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-5230 Filed 3-1-95; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-95-3736; FR-3624-N-03]

Announcement of Funding Awards for the Traditional Indian Housing Development Program Fiscal Year 1994

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

ACTION: Announcement of funding awards.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this document notifies the public of funding awards for Fiscal Year 1994 Indian Housing

Authorities applicants under the Traditional Indian Housing Development Program. The purpose of this document is to announce the names and addresses of the award winners and the amount of the awards.

FOR FURTHER INFORMATION CONTACT:

Bruce Knott, Director, Housing Development Division, Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 755-0068. The TDD number for hearing impaired is (202) 708-0850. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The

Traditional Indian Housing Development program is authorized by sections 5 and 6 of the U.S. Housing Act of 1937 (42 U.S.C. 1437c, 1437d); as amended; U.S. Department of Housing and Urban Development and Independent Agencies' Appropriations Act for Fiscal Year 1994, Section 23, U.S. Housing Act of 1937, as added by sec. 554, Cranston Gonzalez National Affordable Housing Act; sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

The purpose of the competition was to make funding available for the development of new Indian housing units and to replace units approved for demolition/disposition. These Indian Housing Development grants will enable Indian Housing authorities to assist in the development and operation of low-income housing projects in Indian areas. Recipients were chosen in a competition under selection criteria announced a Notice of Funding Availability (NOFA) published in the **Federal Register** on April 20, 1994 (59 FR 18846).

In accordance with section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (Pub. L. 101-235, approved December 15, 1989), the Department is publishing the names and addresses of the recipients which received funding under this NOFA, and the amount of funds awarded to each. This information is provided in Appendix A to this document.

Dated: February 27, 1995.

Joseph Shuldiner,

Assistant Secretary for Public and Indian Housing.

APPENDIX A.—FISCAL YEAR 1994 PUBLIC AND INDIAN HOUSING RECIPIENTS OF FINAL FUNDING DECISIONS

Funding recipient (Name and address)	Amount approved
Program name: New Indian Housing Development	
Statute: U.S. Housing Act of 1937; as added by the Indian Housing Act of 1988	
Metlakatla HA, P.O. Box 59, Metlakatla, AK 99926	\$2,258,704
Metlakatla HA, P.O. Box 59, Metlakatla, AK 99926	3,060,695
Tlingit-Haida Reg HA, Route 1 Box 376, Ketchikan, AK 99901	2,663,667
ASRC HA, Box 677, Barrow, AK 99723	3,482,243
ASRC HA, Box 677, Barrow, AK 99723	3,262,943
Northwest Inupiat HA, P.O. Box 29, Kiana, AK 99749	3,753,000
Interior Reg HA, General Delivery, Ft Yukon, AK 99740	1,867,642
Interior Reg HA, General Delivery, Ft Yukon, AK 99740	1,307,355
Interior Reg HA, General Delivery, Ft Yukon, AK 99740	933,826
Bering Straits Reg HA, P.O. Box 995, Nome, AK 99762	3,264,438
Bering Straits Reg HA, P.O. Box 995, Nome, AK 99762	3,264,438
Bering Straits Reg HA, P.O. Box 995, Nome, AK 99762	3,264,438
Bering Straits Reg HA, P.O. Box 995, Nome, AK 99762	3,264,438
AVCP Reg HA, General Delivery, Kipnuk, AK 99557	3,756,264
Bristol Bay HA, P.O. Box 750, Dillingham, AK 99576	697,133
Bristol Bay HA, P.O. Box 750, Dillingham, AK 99576	1,568,549
Bristol Bay HA, P.O. Box 750, Dillingham, AK 99576	697,133
North Pacific Rim HA, P.O. Box 171, Tatitlek, AK 99677	2,136,645
North Pacific Rim HA, P.O. Box 171, Tatitlek, AK 99677	879,795
Aleutian HA, General Delivery, St. Paul, AK 99660	572,019
Baranof Island HA, P.O. Box 517, Sitka, AK 99835	2,849,637
MOWA Band of Choctaw Indians, Route 1, Box 1080, Mt. Vernon, AL 36560	720,848
MOWA Band of Choctaw Indians, Route 1, Box 1080, Mt. Vernon, AL 36560	1,123,060
Navajo Housing Authority, P.O. Box 387, Window Rock, AZ 86515	1,132,143
Navajo Housing Authority, P.O. Box 387, Window Rock, AZ 86515	2,875,417
Navajo Housing Authority, P.O. Box 387, Window Rock, AZ 86515	10,286,309
Navajo Housing Authority, P.O. Box 387, Window Rock, AZ 86515	5,221,645
Navajo Housing Authority, P.O. Box 387, Window Rock, AZ 86515	8,193,320
Cocopah Housing Authority, P.O. Box AF, Somerton, AZ 85350	3,557,408
Kaibab Paiute Housing Authority, HC 65, Box 122, Fredonia, AZ 86022	1,664,576
Quechan Tribal Housing Authority, 1860 W. Sapphire Lane, Winterhaven, CA 92283	2,924,710
Modoc-Lassen Indian Housing Authority, P.O. Box 2028, Susanville, CA 96130	1,540,331
Modoc-Lassen Indian Housing Authority, P.O. Box 2028, Susanville, CA 96130	1,499,135