In June 1993, in order to address this backlog problem, ODE introduced a comprehensive management action plan for improving the efficiency of its administrative work process. One key item in this plan was introduction of a tier/triage program for applications. The tier/triage program was designed to allow levels of review to be commensurate with the device risk. Three review levels were established in an effort to ensure proper allocation of agency resources among device submissions:

1. Tier I review: For submissions of low risk products, a review that focuses on labeling for intended use.

2. Tier II review: For products associated with moderate risk, a review of labeling and scientific data that includes evaluation of data to substantiate product performance claims.

3. Tier III review: For products associated with high risk or for products with technical features requiring detailed analysis to determine safety and effectiveness, a heightened review of labeling and scientific data. Frequently, advisory panel review and recommendations would be sought as a component of this type of review.

After an assessment of how DCLD would participate in this important management initiative, it was decided that the review of IVD products would be divided between the Tier I and Tier II categories based on the assessment of the need to evaluate specific performance parameters (such as accuracy, precision, analytical sensitivity, and analytical specificity) as part of the review.

Products that did not require a review of performance characteristics prior to use, such as urine cups, and general purpose media, were assigned Tier I status. Products that did require a review of performance characteristics, such as sodium, glucose, hemoglobin and other common analytes, were placed into the Tier II category.

Because classification panels meeting in the late 1970's and early 1980's had already exempted from the requirement for premarket review most IVD's for which performance characteristics were not considered important, only a handful of IVD's were assigned to the Tier I category. These, along with other Tier I products, were exempted from premarket notification in a final rule published in the Federal Register on December 7, 1994 (59 FR 63005) and another final rule published in the Federal Register on July 28, 1995 (60 FR 38896).

The Health Industry Manufacturer's Association (HIMA) strongly believes that there are more premarket submissions for familiar and low risk products that should be subject to a Tier I or similar type review. As a result, last year HIMA developed and provided a flowchart for assigning products into the three tier categories based on classification status, clinical use of the product (stand-alone versus adjunct), and the familiarity of the analyte and method used. Their model is reported to be very reproducible and would provide for a significant increase in the number of products assigned Tier I status.

The DCLD has extensively reviewed the HIMA proposal and has developed a slightly adjusted model also based on a flowchart methodology. Although there are moderate differences when the DCLD model is compared to the HIMA proposal, the effect of the DCLD modified triage flowchart is the same, that is, a significant number of products can be identified that are low risk and/or that represent well understood analytes or methodologies. Therefore, an increased number of products would trigger Tier I reviews.

The DCLD is very interested in ways to redirect its work force to deal with newer and more complex submissions. However, DCLD is concerned with the implications of taking widely used, although familiar products, and subjecting them to a Tier I review and/or exempting them from review. The October 30, 1995, workshop is intended to provide an opportunity for public dialogue on these issues, and will include a presentation by HIMA and distribution of both the HIMA and DCLD flowcharts.

Dated: October 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26927 Filed 10–26–95; 11:12 am]

BILLING CODE 4160–01–F

National Institutes of Health

Notice of Meeting

Notice is hereby given of the second meeting of the Task Force on Genetic Testing of the National Institutes of Health—Department of Energy Joint Working Group on the Ethical, Legal, and Social Implications of Human Genome Research on Tuesday, November 14, 1995, 8:30 am to recess, and Wednesday, November 15, 1995, 8:30 am to adjournment at the Holiday Inn BWI Airport, 890 Elkridge Landing Road, Linthicum, Maryland 21090–2978, (410) 859–8400.

Contact Person: Joshua H. Brown, J.D., Genetics and Public Policy Studies, The Johns Hopkins Medical Institutions, 550 North Broadway, Suite 511, Baltimore, Maryland 21205, (410 955–7894.

This meeting will be open to the public with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should contact Mr. Brown in advance of the meeting.

Dated: October 24, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–26802 Filed 10–27–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: November 6–8, 1995.

Time: 6–8 pm.

Place: The Antheneum Suite Hotel and Conference Center Detroit, Michigan.

Contact Person: Marilyn Semmes, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda MD 20892–7180, 301–496–8683.

Purpose/Agenda: To review and evaluate a grant application.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. The applications and/or proposals and the discussion 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 could constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than fifteen 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 No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: October 23, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–26801 Filed 10–27–95; 8:45 am]

BILLING CODE 4140–01–M

Prospective Grant of Exclusive License: Biomedical Uses of CPX (8-Cyclopentyl-1,3-Dipropylxanthine) and Related Compounds for Cystic Fibrosis and Other Human Diseases

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the inventions embodied in the patents and patent applications referred to below to SciClone Pharmaceuticals, Inc. of San Mateo, California. The patent rights in these inventions have been assigned to the government of the United States of America. The patents and patent applications to be licensed are: ''Method of Treating Cystic Fibrosis Using 8-Cyclopentyl-1,3-Dipropylxanthine or Xanthine Amino Congeners,'' U.S. Patent Application Serial No. 07/952,965 filed 29 Sep 92 (U.S. Patent No. 5,366,977 issued 22 Nov 94); ''A Method of Identifying CFTR-Binding Compounds Useful for Activating Chloride Conductance in Animal Cells,'' U.S. Patent Application Serial No. 08/343,714 filed 22 Nov 94; and all continuations, divisionals, continuations-in-part, and foreign counterparts of these two patent applications.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty (60) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to: J. Peter Kim, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852. Telephone: 301/496–7056, ext. 264; Facsimile: 301/402–0220. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by NIH on or before December 29, 1995, will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent application.

SUPPLEMENTARY INFORMATION: Cystic fibrosis is caused by mutations in the cystic fibrosis transmembrane regulator (CFTR) gene. Chloride (Cl-) and sodium transport across epithelial membranes of an individual afflicted with cystic fibrosis is abnormal. CPX activates impaired Cl- conductance channels and exhibits high potency, low toxicity, and little or no specificity for adenosine receptors.

Many of the present efforts to combat the disease have focused on drugs that are capable of either activating the mutant CFTR gene product or otherwise causing additional secretion of Cl^- from affected cells. Antagonism of the A_1 adenosine receptor has been shown to result in stimulating Cl^- efflux from cystic fibrosis cells. Many of the drugs currently in use or under development function by antagonizing the A_1 adenosine receptor, but lack specificity for the receptor. As a result, they can produce undesirable side effects. Similarly, antagonism of A_1 adenosine receptors will likely have an additional impact on an animal that is unrelated to the cystic fibrosis affliction. Since CPX has little or no specificity for adenosine receptors, it should be effective while minimizing side effects.

Dated: October 20, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–26800 Filed 10–27–95; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. FR–3853–N–02]

Housing Opportunities for Persons With AIDS Program; Announcement of Funding Awards—Fiscal Year 1995

AGENCY: Office of the Assistant Secretary for Community Planning and Development, 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 notice announces the funding decisions made by the Department in a competition for funding under the Fiscal Year 1995 Housing Opportunities for Persons with AIDS (HOPWA) program. The notice contains the names of award winners and the amounts of the awards.

FOR FURTHER INFORMATION CONTACT: Fred Karnas, Jr., Director, Office of HIV/AIDS Housing, Department of Housing and Urban Development, Room 7154, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–1934. The TDD number for the hearing impaired is (202) 708–2565. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The purpose of the competition was to award grants for housing assistance and supportive services by two types of projects: (1) Grants for special projects of national significance which, due to their innovative nature or their potential for replication, are likely to serve as effective models in addressing the needs of low-income persons living with HIV/AIDS and their families; and (2) grants for projects which are part of long-term comprehensive strategies for providing housing and related services for low-income persons living with HIV/AIDS and their families in areas that do not receive HOPWA formula allocations.

The assistance made available in this announcement is authorized by the AIDS Housing Opportunity Act (42 U.S.C. 12901), as amended by the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992) and was appropriated by the HUD Appropriations Act of 1995 (Pub. L. 103–327, approved September 28, 1994) and by the HUD Appropriations Act of 1994 (Pub. L. 103–124, approved October 28, 1993), as amended by Pub. L. 104–19, approved July 27, 1995 (the Rescissions Act). The competition was announced in a Notice of Funding Availability (NOFA) published in the Federal Register on February 16, 1995 (60 FR 9260). Applications were rated and selected for funding on the basis of selection criteria contained in that Notice.

A total of $17,673,957 was awarded for 21 applications under two categories of assistance: $13,406,336 in 16 grants for special projects of national significance; and $4,267,621 in 5 grants for projects which are part of long-term comprehensive strategies for providing housing and related services. In accordance with section 102(a)(4)(C) of the Department of Housing and Urban