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