Dated: October 24, 1995.

Claire V. Broome,

Deputy Administrator, Agency for Toxic Substances and Disease Registry

[FR Doc. 95–26826 Filed 10–27–95; 8:45 am]

BILLING CODE 4163–70–P

Centers for Disease Control and Prevention (CDC)

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Review of the proposed protocol for the study: ''Epidemiologic Study of Adult Leukemia and Workplace Exposure to Ionizing Radiation.''

Time and Date: 9 a.m. to 4:30 p.m., November 28, 1995.

Place: Alice Hamilton Laboratory, Conference Room C, NIOSH 5555 Ridge Avenue, Cincinnati, Ohio 45213.

Status: Open to the public for observation and comment, limited only by space available.

Purpose: The purpose of this meeting is to obtain individual advice and guidance regarding the technical and scientific merits of the proposed epidemiologic study of adult leukemia and workplace exposure to ionizing radiation being conducted by NIOSH investigators. Participants will review the proposed study protocol, recommend changes based on scientific merit, and advise on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Thurman Wenzl, Sc.D., Research Industrial Hygienist, Health-Related Energy Research Branch, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, 4676 Columbia Parkway, M/S R–44, Cincinnati, Ohio 45226, telephone 513/841–4490.

Dated: October 23, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–26809 Filed 10-27–95; 8:45 am]

BILLING CODE 4163–19–M

Lung Cancer and Diesel Exhaust Among Non-Metal Miners; Cohort Mortality Study With Nested Case-Control Study; Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Review of proposed protocol for the study: ''A Cohort Mortality Study with a Nested Case-control Study of Lung Cancer and Diesel Exhaust among Non-metal Miners.''

Time and Date: 9 a.m.–5 p.m., November 27, 1995.

Place: Room 503–A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington DC 20201.

Status: Open to the public for observation and comment, limited only by the space available. The room accommodates approximately 50 people.

Purpose: The purpose of the meeting is to obtain comment and guidance regarding the technical and scientific merits of the study: ''A Cohort Mortality Study with a Nested Case-control Study of Lung Cancer and Diesel Exhaust among Non-metal Miners,'' being conducted jointly by NIOSH and NCI.

Matters to be Discussed: Agenda items include short presentations concerning the study protocol by the study investigators, comments from the review panel members, responses and discussion of the submitted comments, and discussion open to all meeting attendees. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited. Written comments will be part of the review, and should be received by the contact person listed below no later than November 13, 1995.

Contact Person for More Information: Michael D. Attfield, Ph.D., NIOSH Project Director, NIOSH, Division of Respiratory Disease Studies, (DRDS), Mailstop 234, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888, telephone 304/285–5751.

Dated: October 19, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–26810 Filed 10–27–95; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 95N–0343]

In Vitro Diagnostic Devices; Tier/Triage Management Initiative; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to consider a tier/triage management initiative for in vitro diagnostic devices (IVD's). This management initiative is intended to improve the balance between FDA resources and workload based on a tier/triage device risk assessment. The purpose of the workshop is to obtain public comments and suggestions that will help FDA assess potential extensions and applications of the tier/triage management initiative of the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH). A transcript of the meeting will be available from the Dockets Management Branch (address below).

DATES: The public workshop will be held on October 30, 1995, from 9 a.m. to 4 p.m. Submit written notices of participation as soon as possible.

ADDRESSES: The public workshop will be held at the Parklawn Building, conference rooms D and E, 5600 Fishers Lane, Rockville, MD. Submit written requests to make a presentation at the meeting, including an outline of comments, to Kaiser Aziz or Clara Sliva, FAX 301–594–5941. Submit written comments on the management initiative to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. A transcript of the meeting will be available through the Dockets Management Branch. A limited number of overnight accommodations have been reserved at the Doubletree Hotel, Rockville, MD. Attendees requiring overnight accommodations may contact the hotel at 301–468–1100 and reference the FDA meeting group: ''GBG.'' Reservations will be confirmed at the group rate based on availability. Persons with disabilities who require special assistance to attend or participate in the workshop can be accommodated if advance notification is provided to Sociometrics, Inc., Alice Hayes, 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, or FAX 301–608–3542. The availability of appropriate accommodations cannot be assured unless prior notification is provided. There is no registration fee for this meeting.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, or Clara Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084, FAX 301–594–5941.

SUPPLEMENTARY INFORMATION:

Over the past few years, ODE, CDRH, has made an effort to raise the quality of the premarket review of medical devices. In the Division of Clinical Laboratory Devices (DCLD) this has resulted in a movement from a descriptive to a data driven review process with emphasis on using voluntary standards or published design or statistical methodologies as a basis for product review. One consequence of this heightened review process has been an imbalance between workload and workforce resulting in a backlog of submissions.

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