2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.
5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.
5. Pertinent medical and scientific literature.

C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination as to the safety of the finished product.
5. Pertinent medical and scientific literature.

V. Efficacy data.

A. Individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.
5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components.
5. Pertinent medical and scientific literature.

C. Finished drug product.
1. Controlled studies.
2. Partially controlled or uncontrolled studies.
3. Documented case reports.
4. Pertinent marketing experiences that may influence a determination on the efficacy of the finished drug product.
5. Pertinent medical and scientific literature.

VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

VII. If the submission is by a manufacturer, a statement signed by the person responsible for such submission, that to the best of his knowledge it includes unfavorable information, as well as any favorable information, known to him pertinent to an evaluation of the safety, effectiveness, and labeling of such a product. Thus, if any type of scientific data is submitted, a balanced submission of favorable and unfavorable data must be submitted. The same would be true of any other pertinent data or information submitted, such as consumer surveys or marketing results.

In order to avoid duplication, interested persons should not in their submissions include published literature listed in the FDA literature search. An abstract of all such literature will be provided to the panel. Upon request, the panel will be provided with the complete article. Interested persons may, of course, refer to such literature in their submissions by citation.

Submissions or requests for copies of the bibliography of the FDA literature search should be forwarded to:

Food and Drug Administration, Bureau of Drugs, OTC Drug Products Evaluation Staff (BD-109), 5600 Fishers Lane, Rockville, MD 20852.

Submission of data must be on or before April 2, 1973.

(Federal Food, Drug, and Cosmetic Act, sec. 701; 21 U.S.C. 371)

Dated: January 23, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.73-1707 Filed 1-29-73;8:45 am]

Health Services and Mental Health Administration

OCCUPATIONAL SAFETY AND HEALTH

Request for Information on Certain Chemical and Physical Agents

Section 20(a)(3) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(3)) provides that the Secretary of Health, Education, and Welfare, on the basis of information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment. Section 22(c) of the Act authorizes the National Institute for Occupational Safety and Health to develop recommended occupational safety and health standards and to perform all functions of the Secretary of Health, Education, and Welfare, under sections 20 and 21 of the Act. The institute is currently collecting information and data on a number of chemical and physical agents including:

1. Acrolein.
2. Acrylonitrile.
3. Aluminum.
4. Ammonium nitrate.
5. Barotrauma (including decompression tables and standards for divers and tunnel workers).
6. Carbon disulfide.
7. Chlorobenzene.
8. 2,4-dinitrophenol
9. Ethyl benzene
10. Infrared radiation
11. Iron and iron compounds
12. Magnesite
13. Magnesium and magnesium compounds
14. Methyl 2-butyl ketone
15. Nickel carbonyl
16. Ozone
17. Phosphorus penta-chloride
18. Phosphorus penta-sulfide
19. Phosphorus trichloride
20. Tin and tin compounds
21. 1,1,2-trichloroethane
22. Vibration
23. Vinyl chloride

The information and data collected for each agent will be analyzed and evaluated relative to the nine areas listed below:

1. Establishment of safe occupational environment levels for such agents, including levels for acute and chronic exposure to airborne concentrations of the chemical substances, as well as safe work practices concerning direct contact with such substances or physical agents.

2. Establishment of biologic standards; i.e., the levels of such substances, metabolites, or other effects of exposure which may be present within man without his suffering ill effects, taking into consideration (a) the correlation of airborne concentrations of and extent of exposure to such substances with effects on specific biologic systems of man, such as the circulatory, respiratory, excretory, and nervous system, and (b) the analytical methods for determining the amount of the substance which may be present within man.

3. Engineering controls, including ventilation, physical factors, and housekeeping and sanitation procedures, with attention to the technological feasibility of such controls.

4. Specifications for the conditions under which personal protective devices should be required.

5. Methodology, including instrumentation, for air sampling and sample analysis of chemical substances and for quantitation of physical agents.

6. The need for medical examinations for workers exposed to such substances, the frequency of such examinations, and the specific diagnostic tests which should be used, and the rationale for their selection.

7. Work practices or procedures which may be instituted for control of the workplace environment in normal operations, and those which may be instituted when environmental levels are temporarily exceeded, or where peak concentrations of chemical substances in man are reached.

8. The types of records concerning occupational exposure to such agents that employers should be required to maintain.

9. Warning devices and labels which should be required for the prevention of occupational diseases and hazards caused by exposure to such agents.

Any person having information or data which is not readily available in "open scientific literature" in any of the nine areas listed, or in other areas which the

person considers relevant to the establishment of a safe and healthful occupational environment involving the agents set forth above, is invited to submit such information, with accompanying documentation, to the Assistant Director for Research and Standards Development, National Institute for Occupational Safety and Health, Room 10-28, 5600 Fishers Lane, Rockville, MD 20852, within 60 days after publication of this notice.

All information received concerning any agent will be available for public inspection after the development of the respective research analysis report or criteria document.

Dated: January 23, 1973.

MARCUS M. KEY,
Director, National Institute for Occupational Safety and Health.

[FR Doc.73-1689 Filed 1-29-73;8:45 am]

NATIONAL ADVISORY COMMITTEES

Notice of Meetings

The Acting Administrator, Health Services and Mental Health Administration, announces the meeting dates and other required information for the following national advisory bodies scheduled to assemble the month of February 1973.

Committee name	Date, time, place	Type of meeting and/or contact person
Maternal and Child Health Service Research Grants Review Committee.	Feb. 1-2, 9 a.m., Conference Room 8, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Closed. Contact Gloria Wackernah, Room 12A-11, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., Code 301—443-2190.

Purpose. The Committee is charged with the review of all research grant applications in the program areas administered by the Maternal and Child Health Service.

Agenda. The Committee will be performing review of grant applications for Federal assistance and will not be open to the public in accordance with the determination by the Acting Administrator, Health Services and Mental Health Administration, pursuant to the provisions of Public Law 92-463, section 10(a)(2).

Committee name	Date, time, place	Type of meeting and/or contact person
National Advisory Council on Regional Medical Programs.	Feb. 7-8, 9:30 a.m., Conference Room Room G H, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Partially open to the public. Closed for grant review. Contact Mr. Kenneth Baum, Room 11-19, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., Code 301—443-1814.

Purpose. The Council advises and assists the Secretary in the preparation of regulations for, and as to policy matters arising with respect to, the administration of this program. Reviews applications for grants under title IX, and recommends to the Secretary with respect to approval of applications for and the amounts of grants under this title.

Agenda. The Council will hear reports and other business discussed by the Director, Regional Medical Programs Service, regarding the administration of this program, and this portion of the meeting shall be open to the public. The remaining portion of the meeting will be for the review of grant applications, and will not be open to the public in accordance with the determination by the Acting Administrator, Health Services and Mental Health Administration, pursuant to the provisions of Public Law 92-463, section 10(a)(2).

Committee name	Date, time, place	Type of meeting and/or contact person
NIMH Communications Advisory Committee.	Feb. 7-8, 2 p.m., Conference Room 14-105, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md.	Open. Contact Mr. Edwin M. Long, Room 15-105, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., Code 301—443-3788.

Purpose. Advises, consults with, and makes recommendations to the Director, National Institute of Mental Health, on matters of general policy concerning the fields of mental health, scientific and public information, communications, and public health education.

Agenda. Agenda items will include a report on staff activities and consideration of special projects. The Committee will discuss the Child Mental Health Information Interchange, the Tenth Anniversary of Community Mental Health Centers, and the Future Role of the Committee.

Committee name	Date, time, place	Type of meeting and/or contact person
Research Scientist Development Review Committee.	Feb. 22-24, 9 a.m., Center for Advanced Study in the Behavioral Sciences, Palo Alto, Calif.	Closed. Contact Dr. Mary R. Haworth, Room 12-74, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md., Code 301—443-4347.

Purpose. Reviews applications for the Research Scientist Development Awards for support of additional training or experience of behavioral scientists to develop their full capacities for careers devoted to research, and the Research Scientist Awards. Makes recommendations on these programs to the Division of Manpower and Training Programs, National Institute of Mental Health, and the National Advisory Mental Health Council.

Agenda. The Committee will be performing review of grant applications for Federal assistance and will not be open to the public, in accordance with the determination by the Acting Administrator, Health Services and Mental Health Administration, pursuant to the provisions of Public Law 92-463, section 10(a)(2).

Items for discussion are subject to change due to priorities as directed by the President of the United States, or the Secretary of Health, Education, and Welfare.

A roster of members may be obtained from the contact person listed above.

Dated: January 23, 1973.

ANDREW J. CARDINAL,
Acting Associate Administrator for Management, Health Services and Mental Health Administration.

[FR Doc.73-1690 Filed 1-29-73;8:45 am]

Office of the Secretary

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part 3 (Health Services and Mental Health Administration) of the statement of organization, functions, and delegations of authority for the Department of Health, Education, and Welfare (33 FR 15953, October 30, 1968), as amended, is hereby amended with regard to section 3-20, organization and functions, as follows:

In Chapter 3A-00 (Office of the Administrator), section 3A17 entitled "Office of Information (3A17)" is being amended in order to change the name of the office, broaden its activities, and transfer to it the printing and distribution functions from the Office of Procurement and Materiel Management (3A1905). The above changes require a complete replacement of section 3A17, as follows:

Office of Communications and Public Affairs (3A17). Plans, directs, and coordinates the scientific communications, technical information, and health information/education activities of the Health Services and Mental Health Administration. Specifically: (1) Determines policies related to external and internal public affairs and communications activities; (2) plans and carries out all such activities for the guidance of communications and public affairs activities throughout the Administration; (3) identifies program areas and population groups requiring special emphasis in health education and provides guidance, assistance, and support to such special efforts; (4) coordinates all HSMHA scientific and technical information programs, including clearinghouses, libraries, and specialized information centers; (5) establishes operating procedures for the orderly and expeditious processing and dissemination of information/education materials; (6) performs a concept-review and evaluation function of all such materials (films, radio and television materials, publications, magazine articles, news features, exhibits, etc.) to ensure that information/education projects are supportive of program guidelines for major communications activities, and provides administrative management support to