

FDA Advisory Committee Information Line, 1-800-741-8138 (301-439-0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will be discussing appropriate patient populations and outcome measures for clinical trials for drugs to treat alcohol use disorders.

**Procedure:** On April 20, 1999, from 8:30 a.m. to 1:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 6, 1999. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 13, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

**Closed Committee Deliberations:** On April 20, 1999, from 1:30 p.m. to 4 p.m., the committee will review trade secret and/or confidential information relevant to pending investigational new drugs or new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the April 20, 1999, Drug Abuse Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Drug Abuse Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 1999.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 99-8590 Filed 4-6-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

**Name of Committee:** Peripheral and Central Nervous System Drugs Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on April 28 and 29, 1999, 8:30 a.m. to 5 p.m.

**Location:** Holiday Inn Gaithersburg, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

**Contact Person:** Sandra Titus or Tony Slater, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-21), 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On April 28, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 20-884, Aggrenox™ (dipyridamole/aspirin capsules, Boehringer Ingelheim Pharmaceuticals, Inc.), proposed to reduce the combined risk of death and nonfatal stroke in patients who have had transient ischemia of the brain or completed ischemic stroke.

On April 29, 1999, the committee will discuss the safety and efficacy of NDA 20-399, Freedox® (tirilazad mesylate injection, Pharmacia and Upjohn, Inc.), proposed for the treatment of aneurysmal subarachnoid hemorrhage to improve survival and functional outcome in patients with poor neurologic function following the initial hemorrhage.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 21, 1999. Oral

presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 28 and 29, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 21, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 1999.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 99-8501 Filed 4-6-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (60 FR 56605 as amended November 6, 1995, as last amended at 64 FR 14000, dated March 23, 1999). This notice reflects the reorganization of the Maternal and Child Health Bureau.

I. Under Part R, HRSA, Maternal and Child Health Bureau (RM) make the following changes.

#### Section RM-10 Organization and Functions

##### *Office of The Director (RM)*

Provides national leadership and policy direction for the planning, development, implementation and evaluation of the programs and activities of the Bureau. These programs are designed to improve the health of women and childbearing age, infants, children, adolescents, and their families, of children with special health needs, and of persons with hemophilia. Specifically: (1) Oversees the day-to-day management and operations of the Bureau's Offices and Divisions; (2) coordinates all internal functions of the Bureau and facilities effective, collaborative relationships with other health and related programs; (3) establishes a program mission, goals,

objectives, and policy positions consistent with legislation and broad Administration guidelines; (4) serves as the focal point for managing the Bureau-wide strategic planning operation as it relates to long and short range programmatic goals and objectives for the Bureau; (5) works with other Bureaus to further the Agency goals and mission; (6) develops and administers internal operating policies and procedures and provides guidance and direction to Field Office staff, to State Health Officers, and to State Maternal and Child Health and Special Health Needs Directors; (7) serves as principal contact point to the Agency, the Department, Office of Management and Budget (OMB), and the White House on matters concerning the health status of America's mothers and children; (8) directs and coordinates the Bureau's program responsibilities, including the Maternal and Child Health block grants to States, contracts, and other funding arrangements in the areas of research, training, genetics, hemophilia, and health service improvement through regionally and nationally significant projects, a national program to improve emergency medical services for children, a Health Start program designed to strengthen and improve the delivery of health services to improve the outcome of pregnancy, a national program on traumatic brain injury and on injury prevention for children and adolescents, and a national abstinence education program; (9) directs and coordinates the planning, implementation and monitoring of a national maternal and child health data and information system based on State and local jurisdictions; (10) provides direction and serves as the focal point for international matters of concern to the health of mothers, children, and their families; (11) develops a policy statement and an action plan to address the health needs of mothers and children from culturally diverse groups; (12) directs and coordinates Bureau activities in support of Equal Opportunity programs; (13) provides direction for the Bureau's Civil Rights compliance activities; (14) provides information and reports on the Bureau's programs to public, health, education and related professional associations, the Congress, other Federal agencies, OMB, and the White House; (15) coordinates public communications and public affairs activities for the Bureau; (16) administers the implementation of the Privacy Act and the Freedom of Information Act in the Bureau; and (17) performs the executive secretariat functions and coordinates responses to

General Accounting Office (GAO) audit reports and monitors the implementation of GAO recommendations.

#### *Office of Program Development (RM-1)*

Serves as the Bureau focal point for the management of the planning, evaluation, legislation, and legislative implementation activities, including the development, coordination, and dissemination of program objectives, policy positions, reports and strategic plans. Specifically: (1) advises and assists the Bureau Director and the Bureau in the development, coordination and management of legislative planning documents, responses to Departmental and HRSA initiatives, and information papers to support Bureau and Administration goals; (2) interprets evaluation requirements, develops, coordinates, and manages the preparation of the annual evaluation plans and activities, and conducts or contracts for specific evaluation projects related to the performance of MCHB programs; (3) provides staff services, disseminates information, and develops, coordinates, and manages Bureau activities relating to legislation and regulations, and develops and coordinates legislative proposals and regulations; (4) develops, coordinates, and manages Bureau activities related to the development, clearance, and dissemination of Federal Register notices, guidelines, final reports, and periodic and annual reports to other Federal and non-Federal agencies; (5) participates in the development of budget submissions related to the office's functions; (6) coordinates activities closely and continuously with the Office of Planning, Evaluation and Legislation, HRSA, and other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (7) provides liaison with public, private, professional, and voluntary organizations on programs related to MCHB planning and legislative issues; and (8) participates in international health activities of the Bureau.

#### *Office of Operations and Management (RM1)*

Plans, directs, coordinates, and evaluates Bureau-wide administrative and management activities; coordinates and monitors a program and administrative policy implementation; and maintains close liaison with officials of the Agency, and the Office of the Secretary on matters relating to these activities. Specifically: (1) serves as the Associate Administrator's and Bureau principal source for

management and administrative advice and assistance for Headquarters and Field Office staff operations; (2) provides or serves as liaison for program support services and resources, such as procurement of equipment and supplies, space, property, etc.; (3) provides leadership on intergovernmental activities of the Bureau which requires central administrative direction or intergovernmental activities of the Bureau, which require central direction of cross cutting administrative issues affecting program activities; (4) participates in the development of strategic plans, regulatory activities, policy papers, and legislative proposals relating to MCH programs; (5) serves as liaison with the Office of Human Resources Development, HRSA, and coordinates personnel activities for the Bureau; (6) directs, conducts, and coordinates manpower management activities and advises on the allocation of personnel resources including intra- and interagency agreements of Federal assignees to MCH programs; (7) manages the performance appraisal and employee performance management systems; (8) develops and carries out a full range of financial management activities, including the annual budget formulation, presentation, and execution functions; (9) determines State allocation of MCH Block Grant funds based on formula and current census data; (10) is responsible for planning, directing, coordinating, and evaluating Bureau-wide grants management activities, including cooperative agreement operations; (11) coordinates the development and processing of Bureau contract procurement activities and maintains liaison with the Division of Grants and Procurement Management, HRSA; (12) plans, coordinates, and facilitates the Bureau's intra- and interagency agreement activities; (13) provides organization and management analysis, develops policies and procedures for internal operation, and interprets and implements the Administration's management policies, procedures and systems; (14) coordinates the Bureau's program and administrative delegations of authority activities; (15) provides staff services in the operational planning and program analysis; (16) is responsible for paperwork management functions, including the development and maintenance of manual issuances; (17) provides direction regarding new developments in office management activities; (18) participates in international health activities of the Bureau; and (19) responsible for the

coordination of Bureau funds and resources for grants, contracts and cooperative agreements.

*Division of Services for Children With Special Health Needs (RM2)*

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease among children with special health needs, and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems for care for such populations. Specifically: (1) Administers a program which supports the development of systems of care and services for children with special health care needs and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children with special health care needs and their families; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) provides consultation and technical assistance to State programs for children with special health care needs and to local communities, consistent with a Bureau wide technical assistance consultation plan, and in concert with other agencies and organizations; (6) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children with special health care needs and their families; (7) develops and implements a national program for those at risk or living with genetic diseases, including a national program for persons with hemophilia, implementing a system of demonstration projects related to early identification, referral, treatment, education, and counseling information; (8) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act, Supplemental Security Income (SSI), Individuals with Disabilities Education Act (IDEA), and others) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for children with special health care needs, including those with genetic disorders, and their families; (9) promotes the dissemination of information on preventive health services and advances in the care and

treatment of children with special health care needs, including those with genetic disorders, and their families; (10) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children with special health care needs, including those with genetic disorders, and their families; (11) provide a focus for international health activities of the Bureau for services for children with special health care needs and their families; (12) participates in the development of interagency agreements concerning Federal assignees to State MCH programs; and (13) responsible for the administration of funds and other resources for grants, contracts, and cooperative agreements.

*Division of Child, Adolescent, and Family Health (RM3)*

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on the promotion of health and prevention of disease and injury among children, adolescents, and their families with special emphasis on the development and implementation of family-centered, comprehensive, coordinated, community based and culturally competent systems of care for such populations. Specifically: (1) administers a program which supports the development of systems of care and services for children, adolescents, and their families; (2) develops policies and guidelines and promulgates standards for professional services and effective organization and administration of health programs for children, adolescents, and their families; (3) accounts for the administration of funds and other resources for grants, contracts, and programmatic consultation and assistance; (4) coordinates with MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic statutory requirements for State programs for children, adolescents, and their families; (6) provides consultation and technical assistance to state programs for children, adolescents, and their families and to local communities, consistent with Bureau-wide technical assistance consultation plan, working with other agencies and organizations; (7) provides liaison with public, private, professional and voluntary organizations on programs designed to improve services for children, adolescents, and their families; (8) serves as the national focus for improving the health and well-being of adolescents; (9) carries out a national

program on school staff development activities; (10) carries out a national program designed to improve the provision of emergency medical services for children; (11) carries out a national program on traumatic brain injury and on injury prevention for children and adolescents; (12) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services and promote integrated State-based systems of care for children, adolescents, and their families; (13) disseminates information on preventive health services and advances in the care and treatment of children, adolescents, and their families; (14) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to health services for children, adolescents, and their families; (15) provides a focus for international health activities for the Bureau for services for children, adolescents, and their families; and (16) responsible for the administration of funds and other resources for grants, contracts, and cooperative agreements.

*Division of Research, Training and Education (RM4)*

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs related to research, professional and public education activities focusing on the promotion of health and prevention of disease among women of reproductive age, infants, children, adolescents and their families, with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated, community-based and culturally competent systems of care for such population. Specifically: (1) administers a program which supports the development of systems of care and services for children, had their families; (2) develops policies and guidelines and promulgates standards through research, professional and public education and training activities for the Bureau; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in promoting program objectives and the mission of the Bureau; (5) provides liaison with public, private, professional and voluntary organizations on programs and activities; (6) disseminates information on research, professional and public education and training activities to states and

localities; (7) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions; (8) provides a focus for international health activities of the Bureau relating to research, professional and public education and training activities for the Bureau; and (9) responsible for the administration of funds and other resources for grants, contracts and cooperative agreements.

*Division of Perinatal Systems and Women's Health (RM5)*

Provides national leadership in planning, directing, coordinating, monitoring, and evaluating national programs focusing on perinatal, infant and women's health to improve and strengthen the access, delivery, quality, coordination and information of services for the targeted populations, especially for the vulnerable and high-risk. Specifically: (1) administers national programs on perinatal and women's health with an emphasis on infant mortality reduction and prevention; (2) provides policy direction, technical assistance, and professional consultation on Division programs; (3) accounts for the administration of funds and other resources for grants, contracts and programmatic consultation and assistance; (4) coordinates with other MCHB Divisions and Offices in promoting Division programs' objectives and mission of the Bureau; (5) serves as the focal point within the Bureau in implementing programmatic requirements for Division's program; (6) coordinates Division programs within the Agency and with other Federal programs; (7) provides liaison with public, private, professional and voluntary organizations for Division program; (8) disseminates information on Division programs; (9) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals, and budget submissions relating to Division programs; (10) provides a focus for international health activities of the Bureau for Division programs; and (11) responsible for the administration of funds and other resources for grants, contracts, and cooperative agreements.

*Division of State And Community Health (RM6)*

In collaboration with MCHB Division and Offices, serves as the organizational focus for the administration of responsibilities related to the MCH Block Grant to States Program. Specifically: (1) Provides national leadership, direction, coordination, and

administrative oversight related to the development and management of the State MCH Block Grant applications and the annual report; (2) based on review of State Block grant applications and annual reports submitted by States, develops, plans, manages, and monitors a Bureau-wide program of technical assistance and consultation in collaboration with other Bureau Divisions and related health programs; (3) develops and manages a program for the collection, analysis and dissemination of National and State information and data to various constituencies including the public, States, and Congress about the Block Grant to States Program; (4) coordinates within this Agency and with other Federal programs (particularly Title XIX of the Social Security Act) to extend and improve comprehensive, coordinated services in the Block Grant to States Program; (5) develops, plans, manages, and monitors the abstinence only education grant program to the States; (6) develops, plans, manages, and monitors the State Systems Development Initiative (SSDI) grant to the States program; (7) provides leadership and direction to the ten Field Office staffs in concert with the MCHB Division and HRSA; (8) participates in activities related to the Special Projects of Regional and National Significance (SPRANS) program to facilitate the dissemination of effective knowledge related to State MCH functions; (9) manages and monitors interagency agreements of Federal assignees to State MCH program; (10) participates in the development of strategic plans, regulatory activities, policy papers, legislative proposals and budget submissions relating to health services for women of childbearing age, infants, children, adolescents, children with special health care needs and their families; (11) participates in international health activities of the Bureau and coordinates the Pacific Basin activities; and (12) responsible for the administration of funds and other resources for grants, contracts, and cooperative agreements.

*Office of Data and Information Management (RM7)*

Provides national leadership in the identification and analysis of data needs and the utilization and implementation of a data strategy and program focusing on the promotion of health and prevention of disease among women of reproductive age; infants, children, adolescents and their families with special emphasis on the development and implementation of family-centered, comprehensive, care-coordinated;

community-based and culturally competent systems of care for such population. Specifically: (1) develops, coordinates, and maintains a data and information system designed to improve implementation of Title V and other Bureau programs; (2) develops, coordinates, and implements systematic technical assistance and consultation on data and information systems, and evaluation approaches to State and local agencies and organizations or groups concerned with infants, children, adolescents, and children special health care needs; (3) through grants and contracts, provides support for a broad range of data collection, analyses and projects designed to improve the health status of infants, children, adolescents, and children with special health care needs; (4) coordinates and provides for a program of professional consultation and technical assistance through central and field office staff to State and local agencies and organizations; (5) develops, coordinates and disseminates data information; (6) plans, implements and monitors a system of placement of Federal employees assigned to the State health agencies; (7) coordinates and monitors the placement of CDC sponsored epidemiologist in State Agencies; and (8) provides for data program coordination at all levels of Bureau program operations through analyses of program data, trends and other issues concerning scientific and policy matters, the provision of health services and data and information related to the promotion of health and prevention of disease among infants, children, adolescents, and children with special health care needs.

**Section RM-30 Delegations of Authority**

All delegations and redelegations of authority which were in effect immediately prior to the effective date hereof have been continued in effect in them or their successors pending further redelegation. I hereby ratify and affirm all actions taken by any DHHS official which involved the exercise of these authorities prior to the effective date of this delegation.

This reorganization is effective upon date of signature.

Dated: March 25, 1999.

**Claude Earl Fox,**  
*Administrator.*

[FR Doc. 99-8591 Filed 4-6-99; 8:45 am]

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