

relating to the use of the drug in the pediatric population. The statute permits the agency to issue a written request for pediatric studies under section 505A(a) or (c) of the act. A written request is a specific document in which the agency requests submission of certain studies. The studies are designed to provide information on the health benefits of a drug in the pediatric population.

Because the study of oncology drugs in pediatric populations merits special consideration, the agency is publishing this guidance to assist sponsors who wish to undertake pediatric oncology studies.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on pediatric oncology studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cder/pediatrics>, and at <http://www.fda.gov/cber/guidelines.htm>.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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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 65 FR 12021-4 dated March 7, 2000).

This notice reflects the organizational and functional changes in the Northeast Field Cluster (RF1).

Section RF-10 Organization

The Northeast Field Cluster is headed up by the Field Director who reports directly to the Associate Administrator, Office of Field Operations. The Northeast Field Cluster is organized as follows:

- A. Immediate Office of the Field Director (RF14)
- B. Office of Data and Analysis (RF15)
- C. Philadelphia Field Office (RF11)
- D. Boston Field Office (RF12)
- E. New York Field Office (RF13)

Section RF-20 Function

Immediate Office of the Field Director (RF14)

Serves as HRSA's senior public health official in the Northeast cluster, providing liaison with State and local health officials as well as professional organizations; (2) provides input from local, regional and state perspectives to assist the Administrator and the Associate Administrators in the formulation, development, analysis and evaluation of HRSA programs and initiatives; (3) at the direction of the Administrator and/or in conjunction with the HRSA Associate Administrators and the Associate Administrator, Office of Field Operations, coordinates the field implementation of special initiatives which involve multiple HRSA programs and/or field offices (*e.g.*, Border Health); (4) assists with the implementation of HRSA programs in the field by supporting the coordination of activities, alerting program officials of potential issues and assessing policies and service delivery systems; (5) represents the Administrator in working with other Federal agencies, state and local health departments, schools of public health, primary care associations and organizations, community health

centers, and others in coordinating health programs and activities; and (6) exercises line management authority as delegated from the Administrator for general administrative and management functions within the field structure.

Office of Data and Analysis (RF15)

Provides technical assistance, consultation, training to Field Cluster staff, grantees related to data systems, planning, and evaluation; (2) serves as focal point for States and Agency grantees on data and data systems issues related to HRSA program requirements; (3) develops statistical profiles of HRSA grantees in the region, and analysis of Geographic Information Systems profiles and other profiles developed by federal, state and local agencies in the region; (4) develops State profiles; (5) conducts and disseminates, as appropriate, trend analysis of financial data, health indicators, and service data to identify emerging trends among HRSA grantees and health service catchment areas in the Northeast; (6) provides consultation and support to private nonprofit organizations involved in health care delivery around special studies, research, and evaluation related to health disparities; (7) analyzes program related reports; and (8) maintains Field Cluster program related database.

Philadelphia Field Office (RF11)

Directs and coordinates field development and implementation of HRSA programs and activities in 5 states within the Northeast Field Cluster designed to increase access, capacity, and capabilities of local and state health systems and programs serving the underserved populations in the states served by the cluster, including primary care programs, maternal and child health, HIV/AIDS, health facilities construction under the Hill-Burton Program, rural health, and other health related programs in the cluster; (2) provides continuous program monitoring of HRSA health service grants and contracts for compliance with applicable laws, regulations, policies, and performance standards; (3) assists in the implementation and monitors policies related to National Health Service Corps scholarship and loan repayment programs; (4) provides for development, implementation, and monitoring of the annual field work plan related to assigned program areas, including setting objectives responsive to national and field priorities based on guidance provided by appropriate HRSA bureau components and assigns division resources required to attain these objectives; (5) coordinates with

other field office staff and headquarters staff to develop and consolidate objectives crossing program and division lines; (6) serves as source of expertise on health resources and services development, primary health care, maternal and child health, rural health, HIV/AIDS, and health professions programs; (7) establishes effective communication and working relationships with health-related organizations of States and other jurisdictions; and (8) serves as a focal point for information on health resource programs and related efforts, including voluntary, professional, academic and other private sector activities.

Boston Field Office (RF12)

Directs and coordinates field development and implementation of programs and activities in six states within the Northeast Field Cluster designed to increase access, capacity, and capabilities of local and state health systems and programs serving the underserved populations in the states served by the cluster, including primary care programs, maternal and child health, HIV/AIDS, health facilities construction under the Hill-Burton Program, rural health, and other health related programs in the cluster; (2) provides continuous program monitoring of HRSA health service grants and contracts for compliance with applicable laws, regulations, policies, and performance standards; (3) assists in the implementation and monitors policies related to National Health Service Corps scholarship and loan repayment programs; (4) provides for development, implementation, and monitoring of the annual field work plan related to assigned program areas, including setting objectives responsive to national and field priorities based on guidance provided by appropriate HRSA bureau components and assigns division resources required to attain these objectives; (5) coordinates with other field office staff and headquarters staff to develop and consolidate objectives crossing program and division lines; (6) serves as source of expertise on health resources and services development, primary health care, maternal and child health, rural health, HIV/AIDS, and health professions programs; (7) establishes effective communication and working relationships with health-related organizations of States and other jurisdictions; and (8) serves as a focal point for information on health resource programs and related efforts, including voluntary, professional, academic and other private sector activities.

New York Field Office (RF13)

Directs and coordinates field development and implementation of programs and activities in two states, the Virgin Islands, and Puerto Rico within the Northeast Field Cluster designed to increase access, capacity, and capabilities of local and state health systems and programs serving the underserved populations in the states served by the cluster, including primary care programs, maternal and child health, HIV/AIDS, health facilities construction under the Hill-Burton Program, rural health, and other health related programs in the cluster; (2) provides continuous program monitoring of HRSA health service grants and contracts for compliance with applicable laws, regulations, policies, and performance standards; (3) assists in the implementation and monitors policies related to National Health Service Corps scholarship and loan repayment programs; (4) provides for development, implementation, and monitoring of the annual field work plan related to assigned program areas, including setting objectives responsive to national and field priorities based on guidance provided by appropriate HRSA bureau components and assigns division resources required to attain these objectives; (5) coordinates with other field office staff and headquarters staff to develop and consolidate objectives crossing program and division lines; (6) serves as source of expertise on health resources and services development, primary health care, maternal and child health, rural health, HIV/AIDS, and health professions programs; (7) establishes effective communication and working relationships with health-related organizations of States and other jurisdictions; and (8) serves as a focal point for information on health resource programs and related efforts, including voluntary, professional, academic and other private sector activities.

Section RF-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.

This reorganization is effective upon the date of signature.

Dated: May 26, 2000.

Claude Earl Fox,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

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This notice reflects the organizational and functional changes in the Pacific West Field Cluster (RF5).

Section RF—(10) Organization

The Pacific West Cluster is headed up by the Field Director who reports directly to the Associate Administrator, Office of Field Operations. The Pacific West Cluster is organized as follows:

- A. Immediate Office of the Field Director (RF53)
- B. Office of Epidemiology and Data Analysis (RF54)
- C. Division I (RF55)
- D. Division II (RF56)
- E. Division III (RF57)

Section RF—(20) Function

Immediate Office of the Field Director (RF53)

Serves as HRSA's senior public health official in the Pacific West cluster, providing liaison with State and local health officials as well as professional organizations; (2) provides input from local, regional and state perspectives to assist the Administrator and the Associate Administrators in the formulation, development, analysis and evaluation of HRSA programs and initiatives; (3) at the direction of the Administrator and/or in conjunction with the HRSA Associate Administrators and the Associate Administrator, Office of Field Operations, coordinates the field implementation of special initiatives which involve multiple HRSA programs and/or field offices (*e.g.*, Border Health); (4) assists with the implementation of HRSA programs in the field by supporting the coordination of activities, alerting program officials of potential issues and assessing policies and service delivery systems; (5) represents the Administrator in working with other Federal agencies, state and local health departments, schools of public health, primary care associations and organizations, community health