5600 Fishers Lane, Rockville, MD 20857, 301–594–6758, or

Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, e-mail: stifano@cber.fda.gov.

SUPPLEMENTARY INFORMATION: As part of a comprehensive effort to make prescription drugs safer to use, FDA is engaged in several initiatives to make prescription drug labeling a better information source for health care practitioners—clearer, more informative, more accessible, and more consistent from drug to drug. FDA is developing and intends to publish a proposed rule to revise the overall format of prescription drug labeling. It will propose reordering the sections of the labeling, based on the importance of the information to practitioners, and the frequency with which practitioners refer to a section and creating a ''highlights'' section and an index.

FDA also is working on a proposed rule to revise the current requirements for the pregnancy subsection of labeling (see 62 FR 41061, July 31, 1997, announcing 21 CFR part 15 hearing to discuss the category requirements, and 64 FR 23340, April 30, 1999, announcing a public advisory committee meeting to discuss possible changes to pregnancy labeling).

In addition, FDA is developing guidance documents that focus on the content of certain labeling sections. The draft guidance on ''Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics'' provides guidance on, among other things, criteria for including adverse reactions in labeling, presentation of adverse reactions in a table, and organization of the section. This section exists in the current labeling and is expected to continue to exist when the new format for prescription drug labeling is proposed.

At this time, FDA also is developing guidances for the Clinical Pharmacology, Clinical Studies, and Warnings/Precautions sections. The agency expects to publish these draft guidances for comment in the coming months. To date, the agency has focused its efforts on these sections because they typically contain large amounts of important and complex information and there have been significant variations in their format and content across different medical products. Guidances for other labeling sections may be developed later.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the content and format of the adverse reactions section of labeling for human prescription drugs and biologics. 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.

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 the 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.

Dated: June 14, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–15633 Filed 6–20–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1336]

Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pediatric Oncology Studies in Response to a Written Request.'' The draft guidance document provides assistance to applicants intending to respond to a written request from FDA for pediatric studies for a drug that may show potential health benefits in children with cancer. The draft guidance discusses the kind of information applicants should include in their pediatric studies, which, if responsive to a written request, may make the applicant's drug eligible to qualify for an additional 6 months of marketing exclusivity. This guidance is part of the agency's pediatric initiative to generate new knowledge to assist practitioners in the care of children with cancer and to help provide pediatric patients early access to emerging new drugs.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by September 18, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of ''Pediatric Oncology Studies in Response to a Written Request'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Manufacturers Assistance and Communications Staff (HFM–42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 208521448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, FAX 301–827–2520, e-mail: crescenzit@cder.fda.gov, or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0641, FAX 301–827–0644, e-mail: esber@cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pediatric Oncology Studies in Response to a Written Request.'' Section 111 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act), signed into law by President Clinton on November 21, 1997, created section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a), which permits certain marketing applications to obtain an additional 6 months of marketing exclusivity if the sponsor submits requested information

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.

[FR Doc. 00–15629 Filed 6–20–00; 8:45 am]

BILLING CODE 4160–01–F

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