B. Cost Recovery

CERCLA, as amended by SARA, provides for the recovery of costs incurred for response actions at each Superfund site from potentially responsible parties. The recipient would agree to maintain an accounting system that will keep an accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated cost including direct cost, as appropriate for the site. The recipient would also maintain documentation that describes the site-specific response actions taken with respect to the site, e.g., contracts, work assignments, progress reports, and other documents that describe the work performed at a site. The recipient will retain the documents and records to support these financial transactions and documentation of work performed, for possible use in a cost recovery case, for a minimum of ten years after submission of a final financial status report, unless there is litigation, claim, negotiation, audit or other action involving the specific site, then the records will be maintained until resolution of all issues on the specific site.

C. Third Party Agreements

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the grantee and the third party. The written agreement shall at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the grant by the terms of the grant, including requirements concerning technical review (ATSDR selected reviewers), release of data, ownership of data, and the arrangement for copyright when publications, data or other copyrightable works are developed under or in the course of work under a PHS grant supported project or activity.

2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, non-exclusive, and irrevocable license to the Government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal Government purposes.

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant be a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the Government's right in that work.

4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

The written agreement required shall not relieve the grantee of any part of its responsibility or accountability to ATSDR under the cooperative agreement. The written agreement shall, therefore, retain sufficient rights and control to the grantee to enable it to fulfill this responsibility and accountability.

Application Submission and Deadline

The original and two copies of application PHS Form 5161–1 (OMB Number 0937–0189) should be submitted to Ron Van Duyne, Grants Management Officer, Attn: Patrick A. Smith, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 225 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305-2209, on or before August 10, 1998. (By formal agreement, the CDC Procurement and Grants Office will act for and on behalf of ATSDR on this matter.)

A. Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

B. Late Applications: Applications which do not meet the criteria in A.1. or 2. above are considered late applications. Late applications will not be considered.

Where to Obtain Additional Information

To receive additional written information call 1–888–GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to ATSDR Announcement Number 98095. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Patrick A. Smith, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mail Stop E–13, Atlanta, GA 30305–2209, telephone (404) 842–6803, Internet: phs3@cdc.gov.

Programmatic technical assistance may be obtained from Rueben C. Warren, DDS, MPH, DrPH, Associate Administrator for Urban Affairs, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, N.E., Mail Stop E–29, Atlanta, GA 30333 or by calling (404) 639–5060, Internet: rcw4@cdc.gov.

Please refer to announcement number 98095 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the INTRODUCTION through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (Telephone 202–783–3238).

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is: http://www.cdc.gov.

Dated: June 25, 1998.

Georgi Jones,

Director, Office of Policy and External Affairs Agency for Toxic Substances and Disease Registry.

[FR Doc. 98–17459 Filed 6–30–98; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0525]

Draft Guidance for Industry: ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs);'' Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 31, 1998, the comment period for

a notice announcing the availability of a draft guidance for industry entitled ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)'' that appeared in the **Federal Register** of January 5, 1998 (63 FR 236). FDA is taking this action because of the complexity and importance of the issues raised by this draft guidance and to allow interested parties additional time to prepare and submit comments.

DATES: Written comments by July 31, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance for industry ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription drugs: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, or via Internet at burkel@cder.fda.gov;

Regarding prescription biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at stifano@cber.fda.gov;

Regarding restricted medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639, or via Internet at bxt@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 1998 (63 FR 236), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs).'' The draft guidance is intended to assist sponsors of regulated medical products (human drugs, biologics, and medical devices) by describing circumstances in which they may be held responsible for promotional activities performed by a healthcare organization/PBM subsidiary or by a nonsubsidiary healthcare organization/PBM that violate the Federal Food, Drug, and Cosmetic Act and regulations issued thereunder. The draft guidance also reminds medical product sponsors of their responsibility to submit or, in the case of some devices, maintain historical files of promotional labeling and advertising. Following the review of all comments received between January 5 and July 31, 1998, the agency intends to solicit public comment on a new draft guidance document.

Interested persons may, on or before July 31, 1998, submit to the Dockets Management Branch (address above) written comments on this subject. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17413 Filed 6-30-98; 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 (HRSA), (60 FR 56605 as amended November 6, 1995, as last amended at 63 FR 33379–80 dated June 18, 1998). This notice reflects the changes in the Bureau of Primary Health Care (BPHC), Division of National Health Service Corps.

I. Under Division of National Health Service Corps (RC5) delete the current functional statement in it's entirety and replace with the following:

Provides (1) strategic planning and overall policy guidance, and program oversight to the National Health Service Corps (NHSC); (2) initiates national program and policy changes, including regulatory and statutory amendments, as necessary, to ensure NHSC consistency with evolving national health care policy; (3) supports the NHSC National Advisory Council (NAC), which advises the Secretary, DHHS, on national health care policy, particularly as it affects health manpower issues and the NHSC; (4) works with the Office of the Administrator and the Office of the Secretary to ensure that the NAC membership are nationally recognized leaders in national health care policy issues, and in their respective primary health care disciplines; (5) provides national NHSC leadership, integration and coordination with BPHC, HRSA and other Departmental programs serving or impacting the Nation's underserved communities and populations; (6) works directly with Bureau, Agency and intra-Agency, Departmental, and inter-Departmental organizations and staffs, as appropriate, on national policies and strategies affecting underserved populations and development and distribution of primary care clinical personnel; (7) coordinates with the Bureau of Health Professions regarding health professionals education and training, as appropriate; (8) speaks for NHSC with national, regional, State, and local public and private health care professional associations, universities and other health professions training institutions and other groups whose public policy interests relate to primary health care manpower and access issues; (9) articulates NHSC policy interests and issues to a variety of national forums, including universities, foundations, think tanks, and other organizations whose interests in primary and other health care public policy issues have potential for affecting the NHSC; (10) provides policy guidance and support to HRSA field offices, and to State and Regional Primary Care Offices and Primary Care Associations; and (11) coordinates NHSC and Bureau policy on primary and other health care manpower issues, and works with a wide variety of national, regional, State and local constituencies in ensuring their effective implementation.