management technical assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E–18, Atlanta, GA 30305, telephone (404) 842–6595. Programmatic technical assistance may be obtained from Michael E. Dalmat, Dr.P.H., Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mail Stop K–20, Atlanta, GA 30341–3724, telephone (404) 488–5136.

Please refer to Announcement Number 547 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, DC 20402–9325, telephone (202) 512–1800.

Dated: July 10, 1995.

Arthur C. Jackson,

Associate Director for Management and Operations, Centers for Disease Control And Prevention (CDC).

[FR Doc. 95–17415 Filed 7–13–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 91N–0450]

Guideline for Quality Assurance in Blood Establishments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guideline entitled ''Guideline for Quality Assurance in Blood Establishments.'' This guideline is intended to assist manufacturers of blood and blood components, including blood banks, blood centers, transfusion services, and plasmapheresis centers, in developing quality assurance (QA) programs that are consistent with recognized principles of QA and current good manufacturing practice (CGMP). This guideline revises the draft ''Guideline for Quality Assurance in Blood Establishments,'' dated June 17, 1993, and provides general information on procedures and practices that may be useful to blood establishments in developing and administering a QA program.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the ''Guideline for Quality Assurance in Blood Establishments'' to the Congressional and Consumer Affairs Branch (HFM–12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200 North, Rockville, MD 20852–1448, 301–594–1800. Send two self-addressed adhesive labels to assist that office in processing your requests. Persons with access to the INTERNET may request the guideline be sent by return E-mail by sending a message to ''GDE—QA@A1.CBER.FDA.GOV''. The guideline may also be obtained through INTERNET via File Transfer Protocol (FTP). Requestors should connect to the Center for Drug Evaluation and Research (CDER) FTP using the FTP. The Center for Biologics Evaluation and Research (CBER) documents are maintained in a subdirectory called CBER on the server, ''CDV2.CBER.FDA.GOV''. The ''READ.ME'' file in that subdirectory describes the available documents, which may be available as an ASCII text file (*.TXT), or a WordPerfect 5.1 document (*.w51), or both. A sample dialogue for obtaining the READ.ME file with a test based FTP program would be:

FTP CDV2.CBER.FDA.GOV
LOGIN ANONYMOUS
<ANY PASSWORD>
BINARY
CD CBER
GET READ.ME
EXIT

The guideline may also be obtained by calling the CBER FAX Information System (FAX—ON—DEMAND) at 301–594–1939 from a FAX machine with a touch tone phone attached or built-in. Submit written comments on this guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The ''Guideline for Quality Assurance in Blood Establishments'' and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–594–3074.

SUPPLEMENTARY INFORMATION: On January 21 through 22, 1992, FDA sponsored a public workshop on QA in the manufacture of blood and blood products and provided a background information document on quality assurance to all registrants. That workshop was announced in the **Federal Register** on December 13, 1991 (56 FR 65094). FDA developed the ''Draft Guideline for Quality Assurance in Blood Establishments,'' dated June 17, 1993, following the meeting, after considering the discussions at the workshop and comments received. FDA announced the availability of the draft guideline in the **Federal Register** on July 2, 1993 (58 FR 35959), and solicited comments. FDA has revised the draft guideline in response to public comment. The revisions are minor and intended to clarify the document. This guideline, dated July 14, 1995, provides general information on procedures and practices and may be useful to blood establishments in developing and administering a QA program.

To ensure the continued safety of the nation's blood supply, it is essential that blood establishments implement effective control over manufacturing processes and systems. FDA believes that this can be accomplished by each blood establishment developing a well planned, written, and managed QA program designed to recognize and prevent the causes of recurrent deficiencies in blood establishment performance. The emphasis of such a QA program is on preventing errors rather than detecting them retrospectively. The potential public health consequences require that all establishments, regardless of size, invest in QA.

The guideline includes discussions of the following: (1) The general concepts of a quality control/assurance program; (2) the function and reporting responsibilities of the QA unit; (3) the responsibilities of the QA unit in such areas as standard operating procedures, training and education, competency evaluation, proficiency testing, validation, equipment, error/accident reports, records management, lot release procedures and QA audits; and (4) the