DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1341]

Blood Standards; Pilot Program for Licensing and Draft ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From an Outside Supplier;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of a draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier,'' dated June 2000. FDA is announcing its intent to establish a pilot program for licensed manufacturers of Source Plasma seeking to supplement their licenses to include a Red Blood Cell Immunization Program (RBCIP). The pilot program is intended to allow self-certification in lieu of submission to FDA of a detailed biologics license application (BLA) supplement. The draft guidance document provides criteria for participating in the pilot program and for manufacturing, quality control, and labeling of products in an RBCIP. FDA intends to determine if this pilot program streamlines the process for licensing and is more efficient and effective without compromising the health of the donor or product safety, purity, and potency.

DATES: Submit written comments at any time, however, comments are to be submitted by September 18, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier,'' dated June 2000, to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: About participation in the pilot program: Mary Ann Denham, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3543.

About this notice: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier,'' dated June 2000. The draft guidance document is intended to assist those manufacturers who wish to participate in CBER's RBCIP pilot program. CBER is proposing a pilot program that would allow a licensed manufacturer of Source Plasma to self-certify conformance to specific criteria prescribed as part of a pilot program in lieu of submission of a detailed BLA supplement filing. Instead of submitting a BLA supplement with supporting operating procedures and data derived from validation and quality control testing, the manufacturer would submit: (1) An application form (Form FDA 356h); (2) a self-certification statement that provides that the manufacturer is in compliance with all applicable FDA regulations and meets the recommended criteria for RBCIP using immunogen Red Blood Cells obtained from an outside supplier, set forth in the draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier,'' dated June 2000; and (3) a written request to the CBER Director for an exception to filing a detailed supplement. The pilot program provides that FDA will review for completeness Form FDA 356h, the self-certification, and written request for an exception to filing a detailed supplement, and at FDA discretion, will schedule a prelicense inspection within 90 days of receipt of the self-certification to confirm conformance with applicable Federal regulations and the recommended criteria in the draft guidance document. To participate in the program a manufacturer of Source Plasma must: (1) Hold an unsuspended and unrevoked biologics license for Source Plasma; (2) seek to supplement the license to include a RBCIP; (3) plan to use immunogen Red Blood Cells (IRBC), already thawed and deglycerolized, obtained per written agreement from an outside supplier; and (4) have identified an outside supplier of IRBC who holds an unsuspended and unrevoked biologics license for Source Plasma that already includes CBER's authorization for a RBCIP. The manufacturer should be ready for a prelicense inspection at the time it forwards Form FDA 356h, self-certification, and a request for exception to FDA. If, during the prelicense inspection, FDA finds significant deficiencies in quality assurance, manufacturing facilities, or product safety, purity, potency or effectiveness, FDA may withdraw the manufacturer from the pilot program, and the manufacturer will be required to submit a BLA supplement with complete supporting documentation prior to marketing in interstate commerce Source Plasma from donors immunized with IRBC obtained from an outside supplier.

If there is adequate interest in the pilot program, FDA will announce its implementation in the **Federal Register** and will conduct the pilot program for approximately 1 year. At the end of the pilot program period, FDA will evaluate the pilot program for efficiency and effectiveness. If the pilot program proves to be efficient and effective without compromising the health of the donor or product safety, purity, or potency, FDA intends to permit qualified manufacturers of Source Plasma to continue with the self-certification option. FDA is also announcing the availability of a draft guidance document entitled ''Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier,'' dated June 2000. At this time, the draft guidance document is

being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is being issued as a draft level 1 guidance document consistent with the GGP's.

This draft guidance document represents the agency's current thinking on immunization of Source Plasma donors using IRBC obtained from an outside supplier. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. However, manufacturers should conform to the specific criteria set forth in this draft guidance document for voluntary participation in this program. Manufacturers who want to use an alternative approach must submit a detailed BLA supplement under 21 CFR 601.12 or otherwise satisfy FDA that an exemption from that requirement is justified under 21 CFR 640.120. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. CBER intends to revise this draft guidance document based on comments received from the public. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and the pilot program, including those comments expressing interest in participating in the pilot program. Written comments may be submitted at any time, however, comments are to be submitted by September 18, 2000, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: July 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–18059 Filed 7–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4910]

Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3.'' The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999, replacing the interim regulations. The guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Submit written comments concerning this guidance document at any time.

ADDRESSES: Submit written requests for single copies on a 3″ diskette of the guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written comments on the guidance document to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was published as a draft proposal for public comment in the **Federal Register** of December 8, 1999 (64 FR 68696). It has been discussed with the National Mammography Quality Assurance Advisory Committee at two separate meetings (July 1999 and January 2000). The guidance document has been modified from the original draft proposal to address public comments. While there are several clarifying changes in the guidance document, there were no major substantive changes.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the final regulations implementing the MQSA. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1496) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes previously issued ''Compliance Guidance for the Mammography Quality Standards Act Final Regulations Document #3,'' device safety alerts, **Federal Register** reprints, information on premarket submissions