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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2407]

Evaluation and Processing of Post Donation Information Reports; Compliance Policy Guide; Guidance for FDA Personnel; Availability; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new compliance policy guide (CPG) entitled "Evaluation and Processing of Post Donation Information Reports" (section 230.140). This document provides guidance to FDA field and headquarters staff regarding FDA's policy related to the evaluation and processing of post donation information reports for blood and blood components.

DATES: Written comments may be provided at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled "Evaluation and Processing of Post Donation Information Reports" (section 230.140) to the Director, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests, or you may fax your request to 301-827-0482. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. Written comments should be identified with the docket number found in brackets in the heading of this document and should be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharon O'Callaghan, Center For Biologics Evaluation and Research (CBER) (HFM-650), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-1191.

SUPPLEMENTARY INFORMATION:

I. Background

CBER issued a memorandum to blood establishments on December 10, 1993, that provided guidance concerning process control procedures that should be established and maintained for the receipt, evaluation, investigation, and followup of post donation information reports. Post donation information includes information provided by the donor or other source and received or obtained following a donation, or at a subsequent donation during the health history screening process that relates to the suitability of the donor or of the blood or blood component. This CPG provides regulatory guidance relative to the evaluation and processing of this information.

This Level 2 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the evaluation and processing of post donation reports. 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 statutes, regulations, or both.

II. Request for Comments

Written comments concerning the guidance may be submitted to the Dockets Management Branch (address above) at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Written comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of the CPG and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of the CPG (section 230.140) is also available on the Internet by connecting to the ORA home page at “http://www.fda.gov/ora/compliance_ref/default.htm”.

Dated: Aug. 9, 1999
August 9, 1999



Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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