correct ''Amendment No. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–78'' to read ''Amendment Nos. 61–107, 63–30, 65–41, 108–18, 121–280 and 135–79''.

Issued in Washington, DC on June 6, 2001.

Donald Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 01–14656 Filed 6–8–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121 and 135

[Docket No. FAA–2000–7119; Amendment No. 121–281 and 135–80]

RIN 2120–AG89

Emergency Medical Equipment; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule, published in the **Federal Register** on April 12, 2001 (66 FR 19028). That final rule responds to the Aviation Medical Assistance Act of 1998 by requiring that air carrier operators carry automated external defibrillators on large, passenger-carrying aircraft and augment currently required emergency medical kits.

FOR FURTHER INFORMATION CONTACT: Judi citrenbaum, (202) 267–9689.

Correction of Publication

In the final rule FR Doc. 01–8923, beginning on page 19028 in the **Federal Register** issue of April 12, 2001, make the following corrections:

1. On page 19028, in column 1, in the heading section, beginning on line 5, correct ''Amendment No. 121–280 and 135–78'' to read ''Amendment Nos. 121–281 and 135–80''.

Issued in Washington, DC, on June 6, 2001.

Donald Byrne,

Assistant Chief Counsel, Regulations Division.

[FR Doc. 01–14657 Filed 6–8–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 607, 610, 640, 660, and 809

[Docket No. 98N–0581]

Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the general biological product standards applicable to human blood and blood components by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for supplemental (i.e., additional, more specific) testing approved for such use by FDA when a donation is found to be reactive for any of the required screening tests for evidence of infection due to communicable disease agents. The agency also is requiring manufacturers of certain test kits to use reference panels, when available, to verify the acceptable sensitivity and specificity of each lot. This final rule is intended to help protect the safety and ensure the quality of the Nation's blood supply, to enhance the safety of medical devices containing blood or blood components, to provide FDA with clear enforcement authority, and to promote consistency in the industry. Elsewhere in this issue of the **Federal Register**, FDA is publishing a rule requiring blood and plasma establishments to notify donors, including autologous donors, whenever the donor is deferred or determined not to be suitable for current or future donations of blood and blood components.

DATES: This rule is effective December 10, 2001.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

Requirements for testing blood donors for hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (anti-HIV) are currently codified in part 610 (21 CFR part 610), and requirements for performing a serological test for syphilis are codified in part 640 (21 CFR part 640). The agency has issued various guidance documents to registered blood and plasma establishments providing recommendations for testing for antibody to hepatitis B core antigen (anti-HBc), antibody to human T-lymphotropic virus types I and II (anti-HTLV I/II), antibody to hepatitis C virus (anti-HCV), and HIV–1 p 24 antigen. The purposes of the guidance documents are to assist blood and plasma establishments in protecting the safety of the blood supply and to establish policies with the intent of promoting consistency in the industry. These guidance documents represent the agency's current thinking on the appropriate testing of human blood donors for evidence of infection due to various communicable disease agents. Through inspection, we (FDA) determined that blood and plasma establishments generally have been following these recommendations. However, there have been instances where there have been variations in testing and in the determination of suitability of the blood based on the testing results. Accordingly, we proposed a regulation requiring testing consistent with our current recommendations and industry practice.

In the **Federal Register** of August 19, 1999 (64 FR 45340), we published a proposed rule to revise the testing requirements codified in part 610. The proposed rule would require:

- Each donation of human blood or blood component, including autologous donations, to be tested for evidence of infection due to HIV, types 1 and 2; HBV; HCV; and HTLV, types I and II;
- Each donation that tests reactive for any of the required screening tests for evidence of infection due to communicable disease agents, to be further tested using a supplemental (additional, more specific) test that has been approved for such use by FDA;
- The required testing to be performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or meeting equivalent requirements as described by Health Care Financing Administration (HCFA), and registered with FDA in accordance with part 607 (21 CFR part 607);
- Deferral from future donations of donors who test reactive;
- Criteria for release or shipment of human blood or blood components prior to completion of testing under limited circumstances;