



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Bethesda MD 20892

DATE: Nov. 13, 1989

FROM: Donald Hill, Director, Division of Product
Certification, HFB-240 *Donald Hill*

SUBJECT: "Eight-Hour Hold"

TO: Blood and Plasma Inspectors, Center for
Biologics Evaluation and Research

THRU: Joel Solomon, Ph.D., Director, Division of Blood and
Blood Products, HFB-400

The Center for Biologics Evaluation and Research has approved recently an extension of the maximum room temperature hold period following collection of whole blood from six to eight hours prior to preparation of components.

Manufacturers of two blood collection systems submitted supplements to their New Drug Applications (NDAs) with data to support approval of the "eight-hour hold." These systems are the ADSOL^R solution system (anticoagulant CPD), manufactured by Fenwal Laboratories, Division of Baxter Healthcare Corporation and the Nutricel^R system (anticoagulant CP2D), manufactured by Cutter Biological, Division of Miles Inc. The systems have been generically termed as Additive Solution Systems because they utilize a second preservative solution for red blood cell storage in addition to the anticoagulant solution CPD or CP2D.

In both systems the Red Blood Cells may be separated from the plasma within eight hours after room temperature storage. Data submitted from platelets and Factor VIII studies of the plasma support that the plasma is suitable for the manufacture of Platelets, Fresh Frozen Plasma, Cryoprecipitated AHF, and Recovered Plasma.

Terumo Corporation, the manufacturer of the other marketed additive solution system, Optisol^R (anticoagulant CPD), is performing studies to prepare the submission of a supplemental application for the extension of the hold period to their NDA.

No manufacturer has received specific approval for the eight-hour hold for whole blood collected in CPDA-1 at this time. Baxter Healthcare Corp.'s supplemental application for the extension of the hold period to their CPDA-1 NDA is pending. Neither Cutter nor Terumo has submitted a request for the extension for CPDA-1.