

Date: August 8, 1995

From: Director, Center for Biologics Evaluation and Research

Subject: Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma or Source Leukocytes Obtained from Donors with Elevated Levels of Alanine Aminotransferase (ALT)

To: All Registered Blood Establishments

Introduction

In a public meeting on December 3, 1993, FDA's Blood Products Advisory Committee (BPAC) recommended that if donors are voluntarily screened for ALT, and units with elevated ALT are inadvertently collected, FDA should recommend that such units be either a) quarantined and destroyed or, b) labeled to indicate that ALT is elevated and that the contents are for in vitro use only.

The usefulness of the ALT assay for screening blood donors was discussed and examined in detail at the Consensus Development Conference on Infectious Disease Testing for Blood Transfusions sponsored by the National Institutes of Health in January, 1995. The Consensus Statement included a recommendation that "ALT testing of volunteer blood donors should be discontinued".

Subsequently, on March 23, 1995, BPAC concluded that the continuation of ALT testing of Whole Blood and Source Plasma donors is not scientifically justified.

This memorandum is not intended to address the utility of screening donors for serum/plasma ALT values in relation to the safety of blood. FDA does not recommend either for or against ALT testing. However, if a blood establishment elects to perform the ALT test, units with an ALT level greater than twice the upper limit of the normal range (based either on the ALT test kit package insert definition of the upper limit of normal or the results of a community sample sizeable and diverse enough to

validate an alternative upper limit of normal) should not be transfused, and should be labeled either:

1. to indicate that ALT is elevated and that the contents may be used for the manufacture of in vitro diagnostic reagents only, or
2. to indicate that ALT is elevated and that the contents may be used for laboratory research only.

LABELING OF BLOOD AND BLOOD COMPONENTS WITH ELEVATED ALT VALUES

Therefore, FDA is recommending that, if units of Whole Blood, blood components, Source Plasma, Recovered Plasma or Source Leukocytes intended for further manufacturing are tested for ALT, products of those units which have ALT levels greater than twice the upper limit of the normal range (based either on the ALT test kit package insert definition of the upper limit of normal or the results of a community sample sizeable and diverse enough to validate an alternative upper limit of normal), and which are not destroyed, should be labeled with the following statements as appropriate:

1. "ALT ELEVATED"

and

2. "Caution: For Use in Manufacturing Noninjectable Products Only" or, "Caution: For Laboratory Research Only"

Technical questions, information, and comments may be directed to the:

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