Plasma Derived from Therapeutic Plasma Exchange (12/14/84)

Date: December 14, 1984

From: Acting Director,
Office of Biologics Research and Review
Center for Drugs and Biologics

Subject: Plasma Derived from Therapeutic Plasma Exchange

To: All Establishments Collecting Blood for Transfusion
All Source Plasma (Human) Establishments

In an April 1, 1983, Notice published in the Federal Register (Vol. 48, No. 64, page 14048), the Food and Drug Administration (FDA) advised that plasma derived from therapeutic exchange procedures is a biological product subject to the licensing provisions of the Public Health Service Act [42 USC 262 (a)] then collected and shipped for further manufacture into in vitro diagnostic products.

Since the publication of that Notice, several establishments have applied and been considered for licensure. However, inspectional and investigational information gathered over the last six months-has shown that some blood establishments may not be aware of this requirement. Of particular concern was a situation where Therapeutic Exchange Plasma (TEP) was being sold through a broker (middleman). The broker represented the TEP as Recovered Human Plasma (RHP) [Footnote: Recovered Human Plasma is derived from single units of Whole Blood, or Single Donor Plasma, or as a by-product in the preparation of blood components from whole blood collection]. The establishments supplying the TEP were advised that the intended use was for research. Since RHP is, in some situations, used in the manufacture of injectable products, FDA instituted regulatory action to control the violative TEP product.

The purpose of this memorandum is to provide an additional notification to all those establishments which may have an organizational component (blood bank, dialysis unit, or apheresis center) actively engaged in therapeutic plasma exchange procedures.

Important points are as follows:

-- TEP, when intended for further manufacture, is a biological product subject to licensure under the Public Health Service Act [42 USC 262 (a)]

-- Because the TEP is often derived from patients with a disorder that may be transmissible or of unknown etiologic origin, the product represents a potential health hazard.

-- TEP has been limited in its intended use to further manufacture into specific in vitro diagnostic products for which there are no alternate source materials.

-- If the applicable regulatory requirements are not met, FDA may invoke appropriate regulatory action.

-- FDA is not regulating a physician's choice of therapeutic plasma exchange as a medical procedure.

-- TEP is not Recovered Human Plasma and must not be labeled or represented as such.

If this Memorandum was not directed to the office of the most responsible individual (e.g., Hospital Administrator) at the establishment, we request that a copy be forwarded to that office. This will assure that all appropriate components, within an establishment, are notified.

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