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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