



Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

December 18, 2002

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN-2003-05

Joyce M. Eisel, Dr. P.H.
President & CEO
Gateway Blood Association
1880 Craughshire Dr.
St. Louis, MO 63146

Dear Dr. Eisel:

An inspection of your facility was conducted by investigators from the Food and Drug Administration (FDA) on November 18-22 & 26, 2002. This inspection revealed your blood bank collects units of platelets, pheresis, for transfusion and ships some of these units in interstate commerce. The units you distribute in interstate commerce are not covered by an approved license.

Specifically, during the period of January 1, 2002 to October 31, 2002, your records indicate that [REDACTED] units of unlicensed platelets, pheresis were collected for transfusion and shipped to hospitals in Illinois. Shipment of unlicensed blood products in interstate commerce is a violation of the Public Health Service Act (42 U.S.C. 262(a)).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to the Public Health Service Act and the implementing regulations.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

We are in receipt of your November 26, 2002, letter which outlines your corrective action plan. Based upon our initial review, we have no objections concerning your proposed corrective actions. However, we again stress that your firm should not ship platelets, pheresis in interstate commerce until your licensure application has been approved by the Center for Biologics Evaluation and Research (CBER).

Please provide written confirmation of the status of your corrective actions, within fifteen (15) work days of receipt of this letter. Your response should be addressed to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District