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**PURGED**

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

August 14, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 00 - 48**

Robert F. Rave  
Chief Operating Officer and Designated Official  
Stough Enterprises  
1128 Main Street  
Cincinnati, Ohio 45210

Dear Mr. Rave:

The Food and Drug Administration (FDA) conducted an inspection of your facility, Milwaukee Blood Plasma, Inc., located at 2522 W. State Street, Milwaukee, WI, from July 7 - 18, 2000. During the inspection FDA investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FD&C Act) and deviations from the applicable standards and requirements of Subchapter F Parts 600-680, Title 21, Code of Federal Regulations (21 CFR 600-680). The deviations noted on the form FDA-483, Inspectional Observations, issued at the conclusion of the inspection include, but are not limited to, the following:

1. Failure to properly train personnel to assure competent performance of their assigned functions [21 CFR 606.20(b)] in that an employee was observed performing the venipuncture procedure improperly even though the employee had been retrained in that procedure that morning.
2. Collection of plasma from a donor who donated not less than two days apart and more frequently than twice in a 7-day period [21 CFR 640.65(b)(8)].
3. Failure to establish adequate procedures to evaluate donor suitability [21 CFR 606.100(b)] in that collection from the donor occurred less than two days apart and more frequently than twice in a 7-day period.

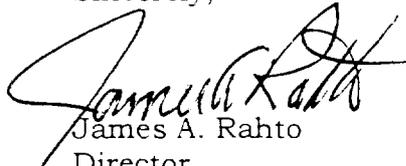
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Neither this letter nor the list of inspectional observations (form FDA-483) is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility as management to assure that your establishment is in compliance with all requirements of the Federal regulations.

You should notify this office in writing within 15 working days of receipt of this letter, of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include license suspension, revocation, and seizure. Your reply should be directed to Compliance Officer Judy E. Heisick at the address indicated on the letterhead.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

JEH/ccl

xc: Peter G. Matson  
Center Manager  
Milwaukee Blood Plasma, Inc.  
2522 West State Street  
Milwaukee, WI 53233