DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

9 11484

April 18, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01- 52

Mr. Michael H. Stough
Chief Executive Officer
Stough Enterprises
1128 Main Street
Cincinnati, OH 45210

Dear Mr. Stough:

The Food and Drug Administration (FDA) conducted an inspection of your facility, Milwaukee Blood Plasma, d.b.a. Plasma Care, located at 2522 W. State Street, Milwaukee, WI from January 30 to February 5, 2001.

During the inspection, FDA investigators documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and deviations from the applicable standards and requirements of Title 21, Code of Federal Regulations, Parts 211 and 600-680, Subchapter F, (21 CFR 211 and 600-680). The deviations noted on the form FDA-483, Inspectional Observations, issued at the conclusion of the inspection included:

1. Failure to appropriately determine the suitability of donors prior to the collection and distribution of the blood product because on January 30, 2001, a donor screener was observed reading the questions too quickly for the donor to respond prior to the screener entering the information into the computerized system and another donor screener was observed asking the questions while the donor was watching the pre-donation video [21 CFR 640.63(d)].

2. Failure to have and/or follow a written standard operating procedure for determining donor suitability in that a donor was permanently deferred for donating more frequently than permitted by regulation but was subsequently reinstated and has been donating regularly since reinstatement [21 CFR 606.100(b)(1)].

3. Lack of proper validation protocols and the maintenance of complete and accurate documentation of the performance of the validation protocols and an analysis of the results for the computerized system, Plasma Center Module [21 CFR 606.160 and 21 CFR 211.68(b)].

4. Failure to establish and implement adequate computer security to assure data integrity in that during this inspection it was observed that an employee was found to have utilized another person's computer access to enter data into the Plasma Center Module computerized record keeping system [21 CFR 211.68(b)]. Review 21 CFR 11 for regulations pertaining to the utilization of electronic records and signatures, and security controls pertaining to both.

Neither this letter nor the FDA-483, Inspectional Observations, issues at the conclusion of the inspection is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility as management to ensure 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 Tyra S. Wisecup at the address indicated on the letterhead.

In addition, a Warning Letter was issued to your firm on August 14, 2000 regarding plasma donations outside the timeframes permitted by regulations. Our record review conducted November 28-30, 2000 revealed on-going violations of this regulation. These findings illustrate the need for additional measures to be taken by your firm. Enclosed you will find a copy of the FDA-483, Inspectional Observations, issued at the close of the January 30 to February 5, 2001 inspection. This FDA-483 lists deficiencies noted in November 2000 regarding such donations and the January/February 2001 inspections regarding other issues.

We have scheduled a meeting on Tuesday, May 1, at 1:00, at the Minneapolis District office to discuss these issues. Please be prepared to discuss the measures your firm is taking to effectively prevent reoccurrence of this illegal donating practice and the above noted deviations. If there is a conflict with. The proposed meeting time please contact Compliance Officer Wisecup.

Sincerely,

James A. Rahto
Director
Minneapolis District

TSW/ccl