DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
HFI-35 m3268n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

DEC 17 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WL-00-17

Catherine Burzik, CEO and President
Ortho Clinical Diagnostics Americas
1001 US Highway 202N
Raritan, New Jersey 08868-0606

Dear Ms. Burzik:

During an inspection of your blood collection establishment, located at Somerset Laboratories, Inc., 612 B. West Katella Avenue, Orange, CA, from August 8 to September 13, 1999, our investigator documented violations of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (CFR) Parts 600-680 as follows:

1. Failure to maintain concurrent records for the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. Specifically, there was no documentation of in-house donor deferral checks of individuals against the appropriate donor deferral listings for each donation prior to July 26, 1999 [21 CFR 606.160(a)(1)].

2. Failure to maintain and/or follow adequate written Standard Operating Procedures (SOPs) [21 CFR 606.100(b)]. Specifically, the in-house checks of individual donors against the appropriate donor deferral registers were only being performed for initial donors.

3. Failure to provide adequate space for the private and accurate examinations of individuals to determine their suitability as blood donors [21 CFR 606.40 (a)(1)].

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. The complete Inspectional Observations FDA Form 483 was issued to Sue Sutton- Jones, Vice President World Wide Compliance (copy enclosed). It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within the 15 working days, state the reason for the delay and the time within which the corrections will be completed. We acknowledge receipt of the letter from you dated September 22, 1999, in response to the FDA-483 observations. This response indicated that some of your corrective actions were in progress at the time (e.g. cubicles rebuilt for privacy), please provide updates and/or estimated times for completion. Your responses will be made a part of your permanent file. If you need any clarification or have any questions regarding this letter contact: Robert W. Nicol, Compliance Officer, at (949) 798-7667.

Your written reply should be sent to:

Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd. Suite 300
Irvine, CA 92612

Sincerely,

Acting District Director

Enclosure

cc: Louise E. Smith, Examiner
State of California
Department of Health Services
Lab Field Services
107 S. Broadway, Room 5016
Los Angeles, CA 90012

Sandra Ellisor, Manager
Somerset Laboratories, Inc.
612 B West Katella Avenue
Orange, CA 92667-4608

Sue Sutton-Jones
VP Regulatory Compliance World Wide
Ortho Clinical Diagnostics
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