

d1769b HFI-35 5/24/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: 1177742

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

May 5, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert E. Carden, President/CEO
Astraea
2201 Westwood Avenue
Richmond, Virginia 23230

Dear Mr. Carden:

The Food and Drug Administration (FDA) conducted an inspection of your Metropolitan Washington Blood Bank facility in Bethesda, Maryland from April 1 to 16, 1998. During the inspection, 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, Parts 211 and 600-680, as follows:

1. Failure to establish and/or maintain an adequate donor deferral system.
2. Failure to establish and/or maintain accurate records of disposition of blood and blood products.
3. Failure to establish and/or follow standard operating procedures (SOPs) concerning:
 - a. blood collections
 - b. SOP change control
 - c. temporary donor deferral
4. Failure to ensure adequate supervisory review of quality control records.

The deficiencies noted were listed on form FDA-483, Inspectional Observations, and presented to and discussed with you at the close of the inspection.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

Mr. Robert E. Carden

Page 2

May 5, 1998

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. Such actions include injunction and/or license revocation.

Please notify this office in writing, within 15 working days of 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 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Wiley T. Williamson, III, Compliance Officer, Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201. Mr. Williamson can be reached at (410) 962-4366, extension 136.

Sincerely,



ELAINE KNOWLES COLE
District Director