



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFI-35m3421r

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

WARNING LETTER

JAN 24 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeanette R. Porretta, President
Pyramid Biological Corporation
6454 Van Nuys Blvd.
Van Nuys, California 91401

W/L 24-00

Dear Ms. Porretta:

During an inspection of Pyramid Biological Corporation located at 4402 Dayton Street, San Diego, California, conducted between the dates of September 27 and 30, 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 (21 CFR) Parts 600-680 as follows:

(1) Failure to follow written standard operating procedures (SOPs) for the collection, processing, compatibility testing, storage and distribution of blood and blood components [21 CFR 606.100(b)]. For example:

(a) During an annual physical of a donor our investigator observed that the physician performing the exam did not explain the potential hazards of the donation procedure in accordance with 21 CFR 640.61; did not ask the donor the HIV high risk questions; and instructed the donor to sign the informed consent without reading the document giving the explanation that they (the donor) had read this form previously.

(b) During this inspection our investigator observed that eight donors were not presented with the high risk information related to HIV/AIDS in accordance with the SOP during the donor history and screening procedure [21 CFR 606.100(b)(1) & 640.63(c)].

(2) Failure to observe, standardize, and calibrate equipment that is used in the collection of blood components in accordance with the Standard Operating Procedures Manual [21 CFR 606.100(b)(15) & 606.60]. Specifically, weekly maintenance was not always being performed on [REDACTED] apheresis machines. For example: machine [REDACTED] did not have weekly maintenance performed the first two weeks in September 1999; machine [REDACTED] did not have weekly maintenance performed the second week in June 1999; machine [REDACTED] did not have weekly maintenance performed the first week in May 1999; machine [REDACTED] did not have weekly maintenance performed the first two weeks in May 1999; and machine [REDACTED] did not have weekly maintenance performed the third week in June 1999.

The above violations are not intended to constitute 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 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. Possible actions include license suspension and/or revocation, seizure, and/or injunction. We acknowledge your response to the Form FDA 483 dated October 6, 1999. While we find your response acceptable (with the exception of comments in item "a" below) this warning letter is appropriate due to the conditions and practices at this facility at the time of inspection.

In addition to the above citations we wish to make the following comments:

(a) While our investigator observed the attending physician fail to properly obtain informed consent during an annual physical exam on only one occasion, we are concerned that this was that individual's pattern of operation. Your response does not address the issue of previous donors examined by this physician who may not have been given proper information related to the hazards of the donation procedure; nor does it address the possible lack of HIV/AIDS exposure determinations of these individuals on the part of the physician.

(b) The high risk questions related to HIV/AIDS are part of the donor suitability determination process. This determination process serves as the first layer of a multi-layered system of safeguards that has been built into the collection, manufacturing and distribution system of blood and blood components to assure a safe blood supply. This system of safeguards also applies to the collection and processing of Source Plasma products. It is unacceptable to disregard this significant step in the collection process.

(c) Equipment that is not properly maintained may not function as designed by the manufacturer and under such circumstances compromise donor and/or product safety. We are concerned that the documentation collected by our investigator supporting Form FDA 483 observation 3 indicates that your QA unit was finding that weekly maintenance was not always being conducted on your [REDACTED] apheresis machines,

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yet no corrective action procedure based upon this knowledge had been implemented at the time of this inspection.

You should notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and time within which correction will be completed.

Your reply should be addressed to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
19900 Mac Arthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,


Thomas A. Allison
Acting District Director

cc: Ms. Mariette S. Devera
Center Director
Pyramid Biological Corporation
4402 Dayton Street
San Diego, California 92115

California State Department of Public Health
Attn: Stuart Richardson
Food and Drug Branch
714 "P" Street, Room 440
Sacramento, CA 95814