



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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July 16, 2001

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jordan B. Killpack
President/CEO
Esolyte, Inc.
4214 South 500 West
Murray, Utah 84123

Ref. #: DEN-01-41

Dear Mr. Killpack:

On March 21-23, 2001, Investigator Cynthia Jim of our office, conducted an inspection of your plasma broker facilities in Murray, Utah. Our inspection documented deviations from the current Good Manufacturing Practices (GMP's) for Blood and Blood Components, Title 21 Code of Federal Regulations (21 CFR), Parts 600 - 680. These deviations cause the blood products manufactured by your firm to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations noted include:

- 1. Failure to maintain concurrently with the performance of each significant step complete and accurate records demonstrating the receiving, component preparation, testing, storage labeling and distribution of each unit of product so that all steps can be clearly traced, as required by 21 CFR 606.160. For example:
- There is no documentation of the activities performed regarding the acceptance and inspection of incoming raw materials. Your SOP for Receiving Materials requires, (X X X X X X X X X X)
(X X X X X X X X X X)
(X X X X X X X X X X)
(X X) There is no indication or documentation that these activities are performed.
- Your computer system did not contain accurate records of the processing (including testing), component preparation, storage or disposition of products. When asked by Investigator Jim regarding the status of several units, your computer system showed the units were located in your freezer, however there was "0" volume available. Mr. Riehle stated that these plasma units were

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utilized and any remaining volume was discarded however he had not updated the information in the computer database.

2. Failure to maintain written standard operating procedures to include methods of component preparation, processing, testing, storage and distribution of blood products for further manufacturing purposes, as required by 21 CFR 606.100. For example:

- Your firm has failed to establish procedures to relate a unit from a donor to its final disposition. Units were found in inventory with more than one label affixed to them, at times obscuring the information contained in the labels below. The name of the collecting facility was missing from the label as well as from the receiving documentation. Information regarding viral marker testing of the units was also obscured by labeling in some instances.
- Labeling procedures have not been established including safeguards to avoid labeling mix-ups.
- Your firm has failed to establish procedures to address the antibody testing of plasma products. There is no written procedure to document the type of testing conducted, the time the test was conducted or the name of the person conducting the test.

3. Failure to include required information on the labeling of blood products, as required by 21 CFR 640.70. For example:

- Your products are not labeled with the correct name. Our inspection found that you have labeled Recovered Plasma as "Plasma (Human)." The correct name for these products is "Recovered Plasma."
- Review of your firm's labels also indicate that they fail to contain information regarding the type of anticoagulant used, the names of any additives, such as Calcium Chloride or Thrombin included in the product, the total volume or weight of plasma and the proper storage temperature.

4. Failure to establish procedures to calibrate or standardize equipment used in the acceptance, processing, testing, storage and distribution of blood products, as required by 21 CFR 606.60. For example:

- Your firm has failed to establish procedures for the scheduling and performance of equipment maintenance and calibration. There were no procedures for the maintenance and calibration of the (~~XXX~~) antibody tester, or for the autoclaves, refrigerators, freezers, thermometers or other measuring equipment used in your facility.

5. Failure to maintain the processing and testing areas in a clean and orderly manner and to be of suitable size, construction and location to facilitate proper operation, as required by 21 CFR 606.40. For example:

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- Our inspection found the carpeting in the processing room was dirty and that there was a live insect on the processing table.
- Our inspection found that your firm did not have a quarantine storage area to be used for rejected materials as required by your Receiving Materials SOP.

The above-identified 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.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

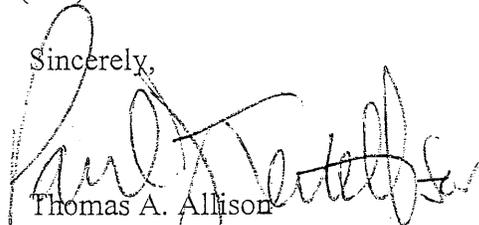
Some of the deficiencies noted during this inspection were listed as deviations and discussed with Mr. Riehle during the prior inspection of your facility in 2000. Mr. Riehle promised corrections both in a written response dated January 8, 2001, as well as verbally to our investigator at the time of the 2000 inspection. We are dismayed to again find that these deviations continue to exist at your facility.

We are in receipt of your firm's May 17, 2001 response to the FD 483. Although you manufacture plasma for use in *in vitro* diagnostic kits, your firm is manipulating and pooling plasma you obtain from various sources. Therefore, your firm is required to be registered. Section 607.65(e) of the CFR applies to the device manufacturers of the *in vitro* diagnostic kits. Your firm is a plasma broker and not a medical device manufacturer as you do not produce the actual diagnostic test kits.

Please notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, Colorado 80225-0087, to the attention of Ms. Regina A. Barrell, Compliance Officer. Ms. Barrell can be reached at (303) 236-3043.

Sincerely,



Thomas A. Allison
District Director

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