



m3190n

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-07

November 12, 1999

John B. Cornish, President
Apheresis Technologies, Inc.
612 Florida Avenue
Palm Harbor, Florida 34683

Dear Mr. Cornish:

We are writing to you because on October 4-7, 12, 1999 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving tubing sets, plasma filters, and blood pumps, which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) regulations for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

QS Regulation/GMPs

1. Failure to establish and maintain procedures to ensure that all purchased or otherwise contracted products or services conform to specified requirements as required by 21 CFR 820.50(a)(1), (2) & (3). For example, there is no written agreement or contract that establishes quality requirements that must be met by suppliers or contractors; that defines the type and extent of control to be exercised over the product or service; and there is no record maintained listing acceptable suppliers or contractors [FDA 483, Item #5].

John B. Cornish
Page 2
November 12, 1999

2. Failure to validate the EtO sterilization process for ATI plasma exchange tubing sets and off-the-shelf software for compiling clinical trial data. Also there are no procedures established and maintained for monitoring and controlling the process parameters for the ATI plasma exchange tubing sets to ensure that specified requirements are met as required by 21 CFR 820.75. For example, there is no documentation covering EtO sterilization and manufacturing processes for the ATI plasma exchange tubing sets. There is no documentation covering Excel application software, or any procedures instituted covering the protection of electronic records or an established back-up system [FDA 483, Item #s 7 & 8].
3. Failure to include in the Device Master Record (DMR) final QA and production specifications for the ATI plasma exchange tubing sets or a reference to the documents location as required by 21 CFR 820. 181(a), (b) & (c) [FDA 483, Item #6].

The specific QS/GMP violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

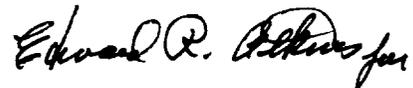
The inspection also determined violations involving your sponsor/monitor activities. You may also receive additional correspondence in the future from the FDA concerning those violations.

John B. Cornish
Page 3
November 12, 1999

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas D. Tolen". The signature is written in a cursive style with a large, prominent initial "D".

Douglas D. Tolen
Director, Florida District