



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M28817

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 13, 1999

Mr. Frederick Brotz, President
Concept Health LLC (Gentell, Inc.)
3600 Boundbrook Avenue
Trevose, Pennsylvania 19053

Dear Mr. Brotz:

On June 30 and July 7, 13, 1999 Food and Drug Administration (FDA) Investigator Edward D. McDonald conducted an inspection of your firm located at 3600 Boundbrook Avenue, Trevose, PA. Your firm manufactures and distributes wound care products (Hydrogel Wound Dressing, Hydrogel Spray Gel and Appligard Amorphous Hydrogel) that are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). As such these devices are subject to the requirements of Title 21 Code of Federal Regulations (21 CFR), including, but not limited to the Quality System Regulation, set forth at 21 CFR, Part 820. At the conclusion of the inspection form FDA-483 Inspectional Observations (copy enclosed) was issued to and discussed with David A. Navazio, Vice President, and Demetrius Trihoulis, Production Manager. The FDA-483 listed deviations to the Quality System Regulation.

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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in 21 CFR, Part 820. as follows:

Failure to validate the manufacturing process of hydrogel [21 CFR 820.75].

Prior to the current inspection your firm was not conducting finished product testing; in absence of an inspection and testing procedure which can verify that a manufacturing process does what it is expected to do, every time, the process must be fully validated. After our review of your records that the investigator obtained during the inspection, we feel that your new inspection and testing procedures, including tests for [REDACTED], appear sufficient to

Page 2
August 13, 1999
Mr. Frederick Brotz
Concept Health LLC (Gentell)
Warning Letter

assure that the hydrogel is manufactured in accordance to specifications. However, these tests should be conducted on all batches (100%) of hydrogel manufactured at your facility. If 100% testing is not conducted we would expect the process to be fully validated in the traditional manner.

Failure to assure that the purified water system consistently meets U.S.P. compendial requirements for Total Organic Carbons (TOC), water conductivity and microbiological limits [21 CFR 820.70].

You should have procedures that indicate the appropriate frequency of testing to assure that your purified water system meets compendial requirements. Testing should be conducted in accordance with your own procedures. Records collected by the investigator indicate that you have had the system tested [REDACTED] however the testing was conducted only once and it did not include a test for microorganisms.

Failure to establish procedures and to conduct periodic quality audits of your firm's quality system [21 CFR 820.22].

This is a repeat violation and was noted in the previous Warning Letter dated February 12, 1999. We recognize that you are a small manufacturer, but that does not excuse your firm from conducting internal audits to determine the effectiveness of your quality system. The audits should be conducted by individuals who do not have direct responsibility for the matters being audited.

Other observations listed on the FDA-483 include:

-Residue of what appeared to be one of your other products (Ease Odor Eliminator) was found on the [REDACTED] filling machine, which is used to fill all products at your firm, but cleaning records indicate that the machine was cleaned.

We feel that this is significant due to the possibility of cross-contamination. We suggest that a second individual inspect the equipment after cleaning or prior to use with medical devices, and document such activities.

Page 3

August 13, 1999

Mr. Frederick Brotz

Concept Health LLC (Gentell)

Warning Letter

-No stability data to support the two-year expiration date for Hydrogel Spray and Appligard.

We understand that you have sent samples of these products to [REDACTED] to conduct accelerated stability studies in an attempt to obtain data to support the two-year expiration date for Hydrogel Spray and Appligard. Please inform us when results of these studies are completed.

At the conclusion of the inspection, Messrs. Navazio and Trihoulis promised to make corrections to the items listed in the FDA-483 by August 13, 1999. Your voluntary corrections will be evaluated during the next inspection of your facility.

We recognize your representations concerning corrective actions, such as your use of [REDACTED] laboratories, improving your quality system, building a clean room, etc. We also recognize your corrective actions since the last inspection, which was accomplished when you ceased manufacturing hydrogel gauze, and submitted the 510(k) for Gentell Hydrogel Wound Dressing. The Center for Devices and Radiological Health (CDRH) will notify you regarding the status of your 510(k) submission.

This letter is not intended to be an all-inclusive list of deficiencies at your firm. As top management, it is your responsibility to ensure adherence to each requirement of the Act and its associated regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of our inspection are symptomatic of serious problems in your firm's manufacturing and quality assurance systems.

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

Until the Quality System Regulation violations are corrected to FDA's satisfaction, and FDA has documentation to establish that such corrections have been made, export approval requests will not be granted. Additionally, Federal agencies will be advised of the Quality System deficiencies at your firm so that they may take this information into account when considering the award of contracts.

Please advise this office in writing within fifteen (15) days of receipt of this letter as to the specific actions you have taken or intend to take to correct the violations. If corrective action

Page 4
August 13, 1999
Mr. Frederick Brotz
Concept Health LLC (Gentell)
Warning Letter

cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Richard C. Cherry, Compliance Officer, at the above address.

Sincerely yours,



Thomas D. Gardine
District Director
Philadelphia District

rcc

Enclosures: Form FDA-483

cc: PA Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104
Attention: Division of Primary Care & Home Health Services
Robert E. Bastian, Director