DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
MADISON

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 26, 1999

WARNING LETTER
CHI-11-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert W. Sessions, President & CEO
Ferris Manufacturing Corporation
1600 W. 83rd Street
Burr Ridge, IL 60521-5848

Dear Mr. Sessions:

During an inspection of your establishment from January 19-28, 1999, our investigator, James Finn, determined that your facility manufactures wound dressings. Wound dressings are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that these 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to take corrective action after determining the following lots failed the quarterly sterility dose audit. Your firm released these lots for distribution without immediately augmenting the irradiation dose or performing a sterility retest as required by your quality assurance procedures when initial sterility tests fail during quarterly sterility dose audits.

   - Lot #03796A1 contained [redacted] of [redacted] samples that failed the sterility test in the report dated March 8, 1996.
   - Lot #01497E1 contained [redacted] of [redacted] samples that failed the sterility test in the report dated February 12, 1997.

2. Failure to adequately validate manufacturing processes. For example:

   - Validation of the cold-seal sterile packaging lines "A" and "E" lack the following: installation qualification of process equipment; identification, evaluation, and quantification of critical process parameters; performance qualification of the process; worst-case challenge(s) to the process; and analysis of results.

- Validation of the heat-seal sterile packaging line "R" lacks the following: identification of specific lots used in the validation; identification of operating parameters; installation qualification of the process equipment; performance qualification of the process; and worst-case challenge(s) to the process. During this validation, your firm performed leak tests at [redacted] inches of mercury, rather than the specified [redacted] inches of mercury. During visual examination for seal integrity, your firm sampled [redacted] devices rather than [redacted] devices that were specified. During seal integrity testing, your firm sampled [redacted] devices rather than [redacted] devices that were specified.

- Validation of the wound dressing membrane production line lacks the following: installation qualification of the process equipment; identification, evaluation, and quantification of critical process parameters; performance qualification of the process; worst-case challenge(s) to the process; and a formal analysis of results.

3. Failure to establish adequate process control procedures to ensure that devices meet specifications. For example, your firm has not established any upper limit(s) for bioburden values disclosed as a result of quarterly bioburden audits.

4. Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, from January 1998 to January 1999, there are no records of audit for 6 of the 18 departments required to be audited in your procedure identified as Spec #R05 entitled, "Quality Assurance System Audits." Departments lacking documentation of audits are Quality Systems, Contract Review, Design Control, Inspection Measuring & Test Equipment, Quality Records and Internal Quality Audits. There are no records to document management review of audit reports.

5. Failure to document cleaning and maintenance of manufacturing equipment. For example, cleaning and maintenance activities of the cold-seal packaging lines "A" and "E" were not documented.

Absorption rate test data, used to support the 3-year expiration dating on the labeling of your products, indicate that all of the test samples exceeded the specified maximum absorption rate of 2 seconds at the end of the 3-month expiry period. Please provide a written response to this observation. Include all planned corrective actions, completion date(s), and product names that have expiration dating.

During this inspection, Investigator Finn informed your firm that the FDA Premarket Notification 510(k) letter K880330, dated 3/23/88, and the FDA Premarket Notification 510(k) letter K900127, dated 5/18/90, specifically state, "This device may not be labeled as a treatment or a cure for vascular stasis ulcers without specific FDA approval for such labeling." This inspection revealed that your products, referred to in K880330 and K900127, are labeled as a treatment or cure for vascular stasis ulcers. You do not have FDA approval for such labeling.

Investigator Finn reported that your firm intends to remove the statements involving vascular stasis ulcers from the labeling of these products. Please provide a written response that indicates your planned completion date(s) for the removal of such statements from the labeling and a list of all your products covered by FDA Premarket Notification 510(k) letters K880330 and K900127.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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 award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments 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.

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, including 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. 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 Michael Lang, Acting Compliance Officer, Food and Drug Administration, 300 S. Riverside Plaza, Suite # 550S, Chicago, IL 60606.

Sincerely,

/s/
Raymond V. Mlecko
District Director