DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

May 8, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph J. Corasanti
President and CEO
ConMed Corporation
525 French Road
Utica, New York 13502

Ref. # - DEN-03-16

Dear Mr. Corasanti:

An inspection of your firm, ConMed Electrosurgery, located at 7211 South Eagle Street, Centennial, Colorado, was conducted between March 10 - 25, 2003, by FDA Investigator Lori A. Medina, and Colorado Department of Public Health and Environment, Environmental Protection Specialists Therese M. Pilonetti and Julie D. Weatherred. This inspection determined that your firm manufactures non-sterile, electrosurgical devices and accessories. These are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated 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/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

Failure to establish and maintain finished device acceptance procedures to assure that finished devices meet acceptance criteria, as required by 21 CFR 820.80(d). For example, your firm failed to adequately conduct a quality review of the device history records in that Hyfrecator 2000 devices which did not meet specifications for voltage output were approved by the quality assurance technicians and released for distribution. Further, these device history records were later reviewed and released by Quality Control pursuant to your "Product Release and Work Order Records Review" procedure, which also failed to detect the non-conforming devices.

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Failure to establish procedures for identifying training needs and to ensure that all personnel are adequately trained to perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, [redacted] responsible for the approval of finished devices for commercial distribution have not been trained in the Operations/Control Procedure entitled, "Hyfrecator 2000" (TP 7-900). This procedure contains the release and testing specifications for the Hyfrecator 2000 which are necessary for the [redacted] to identify out-of-specification testing results.

Failure to establish and maintain procedures to adequately control environmental conditions, as required by 21 CFR 820.70 (c). For example, the results of environmental testing performed in 2001and 2002 as listed in the "Viable Air/Surface Plate Survey Report," indicated several instances of "uncountable overgrown" and "lawn" plates. The procedure, "Validation of Limited Access Areas" states if the test results are over the maximum microbiological contaminant level [redacted]), the [redacted] will complete a "White Room Discrepancy Notice" and forward it to the White Room Supervisor. However, this procedure does not define what is meant by "overgrown," "lawn," or "too numerous to count." The procedure also does not describe what corrective actions the White Room Supervisor is to take if the monitoring limits are exceeded.

Failure to review, evaluate, and investigate complaints involving the possible failure of a device to meet its specifications, as required by 21 CFR 820.198 (c). For example, your complaint procedures require returned Hyfrecator devices to be re-tested according to specifications found in the Operations/Control Procedure, TP 7-900, "Hyfrecator 2000." However, review of documentation of your complaint and failure investigations revealed instances where complete testing of the returned devices was not conducted.

Failure to validate computer software for its intended use according to an established protocol prior to approval and issuance, and document the results of these validation activities, as required by 21 CFR 820.70(i). For example, a software program used to run load curves has not been validated to demonstrate data integrity from the initial point of collection. These load curves were used in design verification activities to assure that design input specifications for power out versus load resistance were met.

Failure to ensure that participants at each design review included representatives of all functions concerned with the design stage being reviewed, as required by 21 CFR 820.30 (e). For example, [redacted] design review meetings conducted in 2003 did not include all required participants as defined within the "Personnel and Responsibilities" section of the Product Development Plan.

Failure to retain all records required to be maintained for a minimum of two years from the date of release for commercial distribution, as required by 21 CFR 820.180 (b). For example, your procedure, "Internal Audit Procedure" states that ' [redacted] All original audit reports, records and memos conducted in 2001 and 2002 were destroyed, according to this procedure.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at

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your facility. It is your responsibility to assure adherence with each requirement of the regulations, as well as other requirements of the Act. Continued distribution of violative devices may result in the initiation of regulatory action without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters regarding medical devices so that they may take this information into account when considering the award of contracts.

You should notify this office in writing within 15 working days of receipt of this letter, of any steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, CO 80225-0087, Attention: Regina A. Barrell, Compliance Officer. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,

B. Belinda Collins
District Director

Cc:

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