



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

AFI 31

12/3/97

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Certified Mail
Return Receipt Requested

1990 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

November 28, 1997

WL-7-8

John F. Wells
President/CEO
Morwell Corporation
8000 South Kolb Road
Tucson, AZ 85706

Dear Mr. Wells:

During an inspection of your firm conducted between October 29 to November 17, 1997, our investigator determined that your firm manufactures a wide variety of general and plastic surgery instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation as prescribed by Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to establish and control procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198]. For example, there is no documentation describing the rationale for not performing investigations or the results of investigations of complaints.
2. Failure to ensure that device master records clearly define all the necessary requirements for the manufacture and other particular activities associated with the production of specific devices [21 CFR 820.181]. For example, there are no assembly instructions, manufacturing specifications, production procedures or other significant quality systems procedures associated with the production of your ultrasound devices.
3. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals [21 CFR 820.20]. For example, your firm has not established any quality system procedures or a quality policy for describing its commitment and objectives to ensure that they satisfy the requirements of the quality system requirements.

4. Failure to establish procedures for quality audits and conduct audits to assure that the quality system is in compliance with established quality system requirements [21 CFR 820.22]. For example, your firm has never performed any audits to determine the effective of your quality system.

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 form FDA 483 issued 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 violation 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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates To Foreign Governments 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, injunctions, 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 reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,



Elaine C. Messa
District Director