



DEC 20 1996

**WARNING LETTER**

Mr. Francois Bataille  
General Director  
Micro Mega, S.A.  
5-12, rue du Tunnel  
25006 Bensancon Cedex  
FRANCE

Dear Mr. Bataille:

During our September 16-20, 1996, inspection of your Cedex, France facility, our investigator determined that your firm manufactures sterile electrolysis needles. This product is defined as a device by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that this device is 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 Good Manufacturing Practice (GMP) regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Our investigator issued a form FDA 483 to you at the conclusion of the above referenced inspection, which cites the following observations:

1. Failure to establish and implement specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example, Micro Mega, S.A. has not validated the epilation needle packaging operation.
2. Failure to establish and implement specification control measures to assure that the design basis for packaging is correctly translated into approved specifications, as required by 21 CFR 820.130. For example, the seals of the electrolysis needle blisters are not inspected for seal integrity, either physically or visually, following ETO sterilization.

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.

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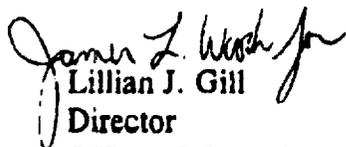
The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigation and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Therefore, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information in to 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.

Please notify this office in writing within 15 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 necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the attention of Mr. Sterling D. Gary, Dental, ENT and Ophthalmic Devices Branch, at the above Gaither Road address.

Sincerely,



Lillian J. Gill

Director

Office of Compliance  
Center for Devices and  
Radiological Health