



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JAN 10 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

WARNING LETTER

Mr. Giovanni Rollier
President
Amplifon S.P.A.
Via Ripamonti, 133
20141 Milan, ITALY

Dear Mr. Rollier

During an inspection of your manufacturing facility located at Via Ripamonti, 133, 20141 Milan, from October 28 through 31, 1996, our investigator determined that your firm manufactures diagnostic audiometers, impedance meters, multi-channel systems for electrodiagnosis, EMG and EP portable systems. These products are devices as defined by 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820 as follows:

1. Failure to establish training programs to provide personnel with the necessary training to perform their assigned responsibilities adequately, as required by 21 CFR 820.25(a). For example, the firm has not established a GMP training program.
2. Failure to review, evaluate, and maintain by a formally designated unit all records of written and oral complaints relative to the identity, quality, reliability, safety, effectiveness, or performance of a device, and to determine whether or not an investigation of a written and oral complaint is necessary, as required by 21 CFR 820.198(a). For example:
 - a. Complaints are not reviewed, evaluated and maintained by a formally designated unit.
 - b. Service and repair requests are not evaluated for their complaint potential.
3. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its performance specifications, as required by 21 CFR 820.198(b). For example, investigation of the root cause of device failures is not performed or documented.

4. Failure to maintain a record of component acceptance and rejection, as required by 21 CFR 820.80(a). For example, the specific test/ examination performed on incoming components and assemblies, the sample size (if any), and the reason for rejection is not consistently documented. There is no scientific basis for the sampling plan used.
5. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.160. For example, records showing the accomplishment of all manufacturing activities, and in-process testing for each unit are not maintained. The database showing the results of finished device testing is not always complete. Final calibration of devices is reportedly documented, however, the documentation is shipped with the device. No copy is maintained.
6. Failure to subject any change in the manufacturing process of a device to a formal approval process, as required by 21 CFR 820.100(b)(3). For example, there is no formal requirement for evaluating the significance of the change, determining the level of validation necessary, execution of the validation according to a protocol, and documentation and retention of the results and conclusions.
7. Failure to perform planned and periodic audits in accordance with written procedures, as required by 21 CFR 820.20(b). For example, the firm does not have internal audit procedures for GMP requirements. No GMP internal audits have been conducted.

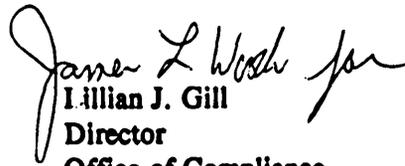
This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the 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 devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected.

Please notify this office within 30 days in writing of the specific steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If the documentation is not in English, please provide a translation to facilitate our review. Please include any and all documentation to show that adequate correction has been achieved. In the case of further corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

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Your response should be sent to Mr. Sterling D. Gary, Consumer Safety Officer, Dental, ENT and Ophthalmic Devices Branch, at the letterhead address.

Sincerely yours.


William J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health