



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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12/25  
D1277B

March 20, 1997

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNCOS AVENUE  
SAN JUAN, P.R. 00901-3223

WARNING LETTER  
SJN-97-09

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Gil P. Gaud Morales  
Owner  
Ear-Tech of Puerto Rico  
P. O. Box 460  
Mercedita, Puerto Rico 00715-0460

Dear Mr. Gaud:

During an inspection of your firm located at Sector La Mora # 9, Mercedita, P. R., on December 19, 30, 1996, and January 23, 1997, our Investigator determined that you manufacture hearing aids. Hearing Aids are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The referenced 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 quality assurance procedures and specifications [21 CFR 820.181(c)].
2. Failure to test finished products for conformance with device specifications [21 CFR 820.160]. The only examination you perform is checking the hearing aids with your own ears. This is inadequate.
3. Failure to identify or provide solutions for quality control problems [21 CFR 820.5(a)(3)]. No records are maintained of hearing aids that fail during the warranty period and require repair. No analysis of failures is conducted to identify problems with components, subassemblies or the design.
4. Failure to maintain device history records [21 CFR 820.184]

Mr. Gil P. Gaud Morales  
March 20, 1997  
Page 2

5. Failure to develop written procedures for the acceptance of components. No records are kept of component acceptance or rejection. [21 CFR 820.80]

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 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 violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

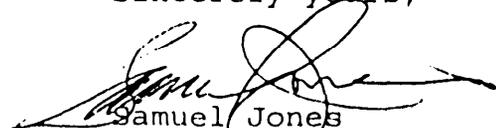
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices 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, 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 Philip R. Lindeman, Compliance Officer, Food and Drug Administration, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

Sincerely yours,

  
Samuel Jones  
District Director