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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER:

November 14, 1996

WL-5-7

Mary A. Munguia
Owner
Clean Pack and Quality
Dental Products
721 Nevada Street, #406
Redlands, CA 92373

Dear Ms. Munguia:

During an inspection of your manufacturing facility conducted between October 15 to 24, 1996, our investigator determined that your firm manufactures dental devices, namely endosseous implants. 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, or the facilities or controls used for manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and control sufficient specification control measures to assure that the design basis for the device and packaging is correctly translated into approved specifications [21 CFR 820.100]. For example, our investigation determined that your firm has no documented evidence which provides a high degree of assurance that the manufacturing specifications and processing controls used in the washing and etching procedures of the endosseous implants will consistently produce a product meeting its pre-determined specifications and quality attributes, traditionally termed validation. Our investigation also determined that your firm has not conducted any testing to determine the bioburden of the device or any package integrity testing to ensure that the packaging provides a proper sterile barrier to prevent contamination of the device.

2. Failure to ensure that finished device inspections are performed correctly to assure that device specifications are met [21 CFR 820.160]. For example, our investigation determined that your firm does not document any finished device testing conducted on the endosseous implants to assure that device specifications are met prior to release to distribution.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. 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 conclusion 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.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared. Also, no requests for Certificates For Products For Export will be approved.

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. Such actions includes, but is 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 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 Boulevard
Irvine, California 92715-2445

Sincerely,


Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814