Food and Drug Administration
New Orleans District Compliance

DEPARTMENT OF HEALTH AND HUMAN SERVICES

4298 Elysian Fields Avenue
New Orleans, LA 70122

d1677b

December 19, 1996

WARNING LETTER NO. 97-NOL-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. N. Edward Hakins, President
Contract Manufacturing, Inc.
2813 DeSiard Street
Monroe, Louisiana 71201

Dear Mr. Hakins:

During an inspection on 10/31-11/5/96, of your facility, located in Monroe, Louisiana, our investigators determined that your firm is not registered with the Food & Drug Administration (FDA) as a Medical Device Manufacturer, nor are your products approved and listed with the Food & Drug Administration. Section 510(k) of the Federal Food, Drug and Cosmetic Act (the Act) requires that all device manufacturers provide premarket notification to FDA. In addition, all device manufacturers are required to register and list their devices with FDA, Section 510 of the Act. Since you have not registered or listed your device with the FDA, your products are deemed misbranded within the meaning of the Act, Section 502(o).

Device registrations and listing forms are enclosed along with instructions for the completion of these forms.

Your manufacturing procedures are subject to the Good Manufacturing Practices (GMP's) Regulations, 21 CFR (Code of Federal Regulations) Part 820. During the above stated inspection, our investigators observed and documented deviations from the GMP's causing your products to be adulterated within the meaning of the Act, Section 501(h). These deviations include: no documentation that device history records are reviewed and approved; no validation of equipment used to seal the water soothers/teethers; no documentation that sterilization does not adversely affect the plastic (half of the complaints concern empty teethers); and no written procedures for the quarantine, acceptance, and/or rejection of components.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations of the Federal Food, Drug and Cosmetic Act.

Federal agencies are advised of the issuance of 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 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 and all violations existing at your firm. 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.

You should notify this office in writing, within 15 working days of receipt of this letter, of the 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 system problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mrs. Olsen.

Sincerely,

Leon L Law
for

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

cc: Joseph H. Hakins
Contract Manufacturing, Inc.
2813 DeSiard Street
Monroe, Louisiana 71201