



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

d119016

Telephone: [718] 965-5300 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Ben Bassat, President
Plastic Solutions, Inc.
43 Windsor Place
Central Islip, NY 11722

February 13, 1997

Ref: 39-NYK-97

Dear Mr. Bassat:

During an inspection of your firm on January 13, 17, and 23, 1997, our investigator determined that your firm contract manufactures the [REDACTED] TMJ exerciser, which is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act ("the Act").

The above-stated inspection revealed that the 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) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to validate processing procedures and controls for the manufacture of molded components to assure that the device conforms to applicable specifications. For example, there were no records of validating operating parameters for the injection molding machine, such as time, temperature, pressure, and speed.
2. Failure to have a "process sheet" control record for the manufacture of the molded setting dial component to assure conformance to establish processing parameters.
3. Failure to have a written operating procedure for the injection molding machine used to manufacture components of the device.
4. Failure to maintain records of the inspection, acceptance, and rejection of components received and used in the manufacture of the device to assure conformance to specifications.

5. Failure to have written procedures for and records of the routine inspections and calibrations of measurement equipment used in the manufacture of the device. This includes the Temtek temperature control unit, the pyrometer used for verifying injection molding machine temperatures, and the vernier caliper used during final assembly of the device.
6. Failure to have written procedures for and records of the scheduled cleaning and maintenance of the injection molding machine and the molds used to manufacture components of the device.
7. Failure of the current schematic drawing of the device to be signed and dated by a designated individual to indicate approval of the design and specifications.
8. Failure to review, evaluate, and maintain by a formally designated unit all records of written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of the device including a written record of each investigation made and reply to complainant. For example, in October 1996, five device units were returned due to leakage and there are no records of the receipt, handling and outcome of the complaint.

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 detailed further in the attached Form FDA 483 that was issued to and discussed with you 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. 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 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

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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 the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attn: Bruce A. Goldwitz, Compliance Officer.

Sincerely,



Charles W. Sedgwick
Acting District Director

Attachment: Form FDA 483

cc:

