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DEPARTMENT OF HEALTH & HUMAN SERVICES

M2837 n

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 4, 1999

Jesse Ross, D. Sci.
President
Diapulse Corp. of America
321 E. Shore Road
Great Neck, NY 11023

Ref: NYK 1999-58

Dear Mr. Ross:

During our May 7 through June 11, 1999 inspection of your facility located in Great Neck, New York, our investigator determined that your firm manufactures/services the Diapulse therapeutic device. The Diapulse is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection determined that the Diapulse 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 current good manufacturing practice, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

At the conclusion of the inspection, the investigator presented the enclosed Inspectional Observations (Form FDA-483) to you, and discussed his findings. The following violations were noted:

1. Failure to establish a quality system for the production of the Diapulse device to ensure that the device conforms to specified requirements [21 CFR 820.5].
2. Failure to establish procedures for identifying training needs to ensure all personnel are adequately trained [21 CFR 820.25(b)].
3. Failure to establish and maintain procedures for the identification, documentation, review and approval of design changes before implementation, as required by 21 CFR 820.30(I). For example, there is no procedure in place to control design changes for the Diapulse device.
4. Failure to establish and maintain procedures to control all documents such as document review, approval, distribution, and changes [21 CFR 820.40].

5. Failure to establish and maintain procedures to ensure that all purchased components and services conform to specified requirements [21 CFR 820.50].
6. Failure to develop, conduct, and monitor production processes of the Diapulse device to ensure it conforms to its specifications [21 CFR 820.70]
7. Failure to establish and maintain procedures to ensure that test equipment is routinely calibrated, inspected, checked, and maintained [21 CFR 820.72].
8. Failure to establish and maintain procedures for acceptance of incoming components used in the manufacture of the Diapulse device [21CFR 820.80(b)].
9. Failure to establish procedures for implementing corrective and preventive action [21 CFR 820.100].
10. Failure to establish and maintain procedures to control labeling activities relating to the Diapulse Device [21 CFR 820.120].
11. Failure to establish and maintain procedures to ensure that mix-ups, damage, or other adverse effects to the Diapulse device do not occur during handling [21 CFR 820.140].
12. Failure to maintain and have readily available for inspection, records pertaining to the production and distribution of the Diapulse device [21 CFR 820.180].
13. Failure to maintain Device Master Records for each model of the Diapulse device. The Device Master Records lack complete drawings, specifications, quality assurance procedures, maintenance and servicing procedures. In addition, there is no formal system in place for the approval of the Device Master Record for each model produced [21 CFR 820.181].
14. Failure to establish procedures to ensure that Device History Records are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record [21 CFR 820.184].
15. Failure to establish procedures for receiving, reviewing, and evaluating complaints [21 CFR 820.198].
16. Failure to establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements [21 CFR 820.200].

The violations of the Act described above are not meant to be an all-inclusive list of deficiencies by your firm. 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