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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *RF*

March 31, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 19

Dr. Charles Wilson
Chairman of the Board
Bio-Research, Inc.
161 East Chicago Street, #44F
Chicago, Illinois 60611

Dear Dr. Wilson:

During a Food and Drug Administration (FDA) inspection of your firm in Milwaukee, WI, that concluded on January 8, 1998, our investigator determined that your firm manufactures the BioPAK System. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed the following violations:

- The BioPAK System is adulterated within the meaning of Section 501(f)(1)(B) in that it is a Class III device under Section 513(f) and does not have an approved application for pre-market approval in effect pursuant to Section 515(a) or an approved application for an Investigational Device Exemption under Section 520(g).
- The BioPAK System is misbranded within the meaning of Section 502(o) in that a notice or other information respecting the modification to the

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device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(i). The device is further misbranded within the meaning of Section 502(o) in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by 21 CFR 807.81(a)(3)(ii).

Your firm failed to obtain a new 510(k) or pre-market approval after making significant changes to the BioPAK System. Analysis software, i.e., "The Interpreter," was added to the system to aid in the diagnosis of temporomandibular joint disorders. In addition, your firm is promoting an indication for use ("implants") that is not covered under your existing 510(k)'s.

The SonoPAK device received 510(k) clearance on May 15, 1991 (K905657/A). A copy of the 510(k) letter is enclosed. This letter informed Bio-Research that "...a new 510(k) is necessary if you intend to make any change to the labeling, promotional material, or indication statement for the SonoPAK/QS, SonoPAK." The letter also states that a new 510(k) is necessary for "...any change to your device's system requirements specification including software and firmware."

This letter is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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. Also, no requests for Certificates for Product 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 FDA 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 steps you are taking to correct the problem. Additionally, please advise us

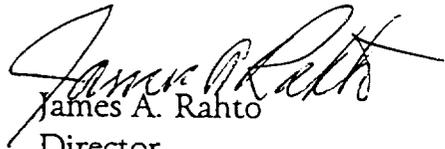
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of any action you have taken or plan to take to address previously distributed product.

Your response should be sent to Timothy G. Philips, Acting Compliance Officer, at the address on the letterhead.

Sincerely,


James A. Rahto
Director
Minneapolis District

TPG/ccl

Enclosure: Letter, West to Radke, 5/15/91

xc: James Oswald
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