



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94714d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 7, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-28

Ian B. R. Campbell, General Manager
Tianshi Health Products, Inc., USA
917 134th Street Southwest, Suite #A-8
Everett, Washington 98204

WARNING LETTER

Dear Mr. Campbell:

An inspection conducted at your facility at Tianshi Health Products, Inc., USA, 917 134th Street Southwest, Suite #A-8, Everett, Washington, on February 19-20, 2004, by the Food and Drug Administration (FDA) revealed a serious regulatory problem involving the product known as the Acupoint Treasure. Under a United States federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is a medical device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, or is intended to affect the structure or function of the body. See section 201(h) of the Act, 21 U.S.C. 321(h). Specifically, according to its labeling, the Acupoint Treasure is a "pocket medical acupuncture appliance" that claims to lower blood pressure, eliminate inflammation, relieve pain, improve microcirculation, and treat diseases, including peri-arthritis of humeroscapularis, headache, waist pain, and nerve pain.

The law requires that manufacturers of certain medical devices or initial importers of certain foreign-made medical devices obtain marketing approval or clearance for their products from FDA before they may offer them for sale or import them into the United States. This helps to protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that there is marketing clearance or approval in effect for the Acupoint Treasure. Our inspection revealed that 2000 Acupoint Treasures were nonetheless imported and delivered to your Everett, Washington facility in August 2003 from your facility Tianjin Tianshi

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Bioengineering Co., Ltd., Tianjin, China. These Acupoint Treasures were declared as "TIANSHI ACUPOINT TRESURE MASSAGE" with product code "89I{} {}SA" under entry number FN5-0105653-8. The inaccurate declaration on the entry caused these unapproved medical devices to enter the United States without review by the FDA. Two hundred of these devices were subsequently exported to Canada.

Because the Acupoint Treasure medical devices do not have marketing clearance or approval from the FDA, they violate United States law. In legal terms, the devices are misbranded under section 502(o) [21 U.S.C. 352(o)] and adulterated under section 501(f)(1)(B) [21 U.S.C. 351(f)(1)(B)] of the Act. Your devices are misbranded under the Act because you did not submit a premarket notification under section 510(k) of the Act. Until you submit a section 510(k) premarket notification and FDA reviews it and notifies you that your device is substantially equivalent to other legally marketed devices, your devices are also adulterated under the Act because the law requires, and you do not have, an approved premarket approval application that shows your device is safe and effective. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency (21 CFR 807.81(b)).

Until these serious violations of the Act are corrected, future shipments of the Acupoint Treasure may be refused admission to the United States. This serious violation of the law may also result in FDA taking regulatory action without further notice, including seizing your product inventory. Federal agencies are informed of the issuance of all warning letters about drugs and medical devices so they may consider this information when awarding government contracts.

You should take prompt action to correct this deficiency. You should notify this office within fifteen (15) working days from receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. 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.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket review requirements for your device and does not necessarily address other obligations you have under the law. The kind of information you need to submit in order to obtain clearance or approval for your device is described on FDA's Internet website at www.fda.gov/cdrh/devadvice. The FDA will evaluate this information and decide whether your product may be legally marketed. You may obtain general information about all of FDA's requirements for manufacturers and distributors of medical devices by contacting our Division of Small Manufacturers and International Consumer Assistance (DSMICA) at (800) 638-2041 or through the Internet at <http://www.fda.gov>.

Ian B. R. Campbell, General Manager
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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen

for Charles M. Breen
District Director

cc: Percy K. Chin, Chief Executive Officer
Tianjin Tianshi Bioengineering Company, Ltd.
Henderson Building
18 Jianguomennei Avenue
Tower 1, Floor 20
Beijing, China 100005