



Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

Susan Makarian
Z'Strong International
9650 Flair Drive
Suite 303
El Monte, California 91731

AUG 25 2000

RE: k974523

Dear Ms. Makarian:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received a recent inquiry about the status of your product, accompanied by a copy of a promotional brochure for Z'Strong International's Bioelectric Discharger. We have also reviewed the company's website promotion of the discharger. The discharger is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act.

FDA cleared the device for marketing with the following intended use language: "Z'Strong Bioelectrical Discharger is a battery operated device for muscle relaxation."

The brochure that we have reviewed makes the following claims: "The Z'Strong Bioelectrical Discharger uses the bioelectricity that the human body produces to *regulate and balance your blood pressure*. . . Regularly releasing bioelectric energy at this *hypertension groove* has been shown to have an amazing effect on the vital energy circulation, *resulting in the regulation and stabilization of blood pressure*." It says, "Take advantage of the Z'Strong Bioelectrical Discharger to *take control of your hypertension and to keep it stabilized*." (Emphasis added.) In addition, your brochure calls the device "an alternative to medication for controlling your high blood pressure – *without the dangerous side effects*." (Emphasis in original.)

The Center has conducted continued correspondence with you and Arthur King Ma, former consultant for Z'Strong, regarding claims for this product. We have repeatedly advised you that the claims for reduction, regulation or management of blood pressure are inappropriate because they change the intended use of the device.

The agency's regulations at 21 CFR 801.4 provide that the "intended use" of a device refers to the objective intent of the persons legally responsible for the labeling of a device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may be shown by, for example, labeling claims, advertising matter or oral or written statements of such persons or their representatives."

During CDRH's review of the 510(k) submission for the device, the reviewer advised Mr. Ma that the claims related to effect on blood pressure could not be cleared. Mr. Ma, in a letter dated March 18, 1998, made a commitment to FDA that all claims related to hypertension would be removed from the company's 510(k). This letter of commitment is included in the company's submission and is part of FDA's official record. CDRH issued another letter, dated October 4, 1999, by which Mr. Ma was again notified that the claims for reducing blood pressure were not cleared and would require the submission of a new 510(k).

On October 9, 1999, Mr. Ma responded that the company would remove the claim from its website and would file a new 510(k) for the claim related to reducing blood pressure.

In a letter to you dated February 18, 2000, our office advised you that Z'Strong's promotional material and an advertisement for the device continued, as of the end of 1999, to make claims that the devices can reduce blood pressure. That letter also advised you that continued promotion of the device for claims of reducing blood pressure caused your products to be misbranded and adulterated within the meaning of sections 502(o) and 501(f)(1)(B), respectively, of the Act. You were advised to cease distribution of any promotional materials making hypertension related claims unless and until you received clearance for the blood pressure claims or for any other change in the product's intended use. You were also advised that to receive additional claims for the product, Z'Strong would have to submit a new 510(k) to the Center's Office of Device Evaluation. The company did not respond to that letter.

As of August 21, 2000, the company's website at www.zstrong.com continues to make the claims that you have been instructed repeatedly to cease. Also, as noted, we have reviewed several brochures that appear to have been recently distributed. There are claims for the device for hypertension in the company's words and in the testimonials posted on the website and in the print materials.

The company's continued misrepresentation, on its website and in its print materials, of the intended uses of the device have caused the discharger to be misbranded and adulterated within the meaning of sections 502(o) and 501(f)(1)(B), respectively. The device is misbranded under section 502(o) because the company has not submitted a notice or other information respecting the use of the device for reducing blood pressure, as is required in section 510(k) of the Act. It is adulterated under 501(f)(1)(B) because it is a class III device as provided by section 513(f) of the Act and is under neither an approved premarket approval application, as required by section 515 of the Act, nor an approved investigational device exemption, as provided by section 520(g) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies associated with Z'Strong's devices. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter may also be reflected in other promotion and advertising materials used by your company. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

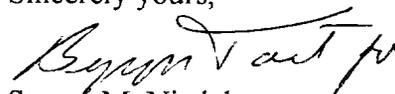
Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps that you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective actions cannot be

completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District office. Please send a copy of your response to the District Director, Los Angeles District Office, Food and Drug Administration (HFR- PA240) 19900 MacArthur Blvd, Ste 300, Irvine, California 92715.

Sincerely yours,



Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health