



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 24 1998

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

WARNING LETTERVIA FEDERAL EXPRESS

Mr. Douglas L. Myers
 President
 Jazmon Technologies, Incorporated
 938 Amherst Road, N.E.
 Massillon, Ohio 44646

Re: CTR 2000™ Wrist Exercise
 Device

Dear Mr. Myers:

The Food and Drug Administration (FDA) has reviewed the March 24 response from your legal representative, Mr. Kirkpatrick W. Dilling, Dilling and Dilling, Chicago, Illinois, to our letter dated March 13. We find your response unacceptable and we have the following comments.

The CTR 2000™ is manufactured by Jazmon Technologies, Incorporated (Jazmon) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

As we pointed out in our March 13 letter, the CTR 2000™ is defined in the regulations at 21 CFR 890.5370 as non-measuring exercise equipment intended for medical purposes such as to redevelop muscles or restore motion to joints, or for use as an adjunct treatment for obesity. Examples include mechanical treadmills, manually propelled exercise bicycles, and parallel bars. When used and/or advertised for the above intended use(s), the product is exempt from the 510(k) premarket notification requirements.

By promoting the CTR 2000™ for such medical uses as relieving the symptoms of carpal tunnel syndrome and/or for the relief of the pain, numbness, tingling, and other stress symptoms associated with carpal tunnel disease, Jazmon has changed the intended use of the device and causes the product to become subject to the 510(k) premarket notification filing requirements as defined under 21 CFR 807.81(a)(3)(ii).

The following quotations taken from your literature and from our previous letter are repeated here:

-“It was developed to help relieve the symptoms of Carpal Tunnel Syndrome;” (from the Quick Start Reference Guide)

-“Relief now possible for Carpal Tunnel Syndrome.” “...fast relief from hand/wrist pain, numbness, tingling, and loss of grip in less than 3 minutes per hand;” (from the Jazmon catalogue)

-“The Dr. Myers CTR 2000™ provides passive, measured, bilateral stretching to help

relieve hand/wrist pain, numbness, tingling, and other stress symptoms often associated with Carpal Tunnel Syndrome" (from the Instructions for Use Booklet).

The CTR 2000™ is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The CTR 2000™ is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your CTR 2000™ device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by 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, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. 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 Mr. Steven E. Budabin, Consumer Safety Officer, 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 Cincinnati District Office. Please send a copy of your response to the District Director, Food and Drug Administration, Cincinnati District Office (HFR-MA400), 1141 Central Parkway, Cincinnati, Ohio 45202-1097.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health