



MAY 12 2004

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

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Dale Miller  
President and CEO  
The Chin-Up Strip (DMI)  
1820 Ridgemill Terrace  
Dacula, Georgia 30019

Dear Mr. Miller

We received your letter dated January 22, 2004, in which you respond to our untitled letter of December 22, 2003. In your response, you state: "It is our intention, therefore, to file a premarket notification submission (section 510(k)) within the next 30 days claiming substantial equivalence to products already on the market for similar intended uses." Because you have not in fact filed a premarket notification submission, your continued marketing of the Chin-Up Strip® violates the Federal Food, Drug, and Cosmetic Act (the Act).

According to your Internet website, the Chin-Up Strip® is an effective treatment for mild obstructive sleep apnea. Your product is therefore a medical device as defined by section 201(h) of the Act 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 because it is "intended to affect the structure or any function of the body."

The law requires that manufacturers of medical devices obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that newly-introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Your device is adulterated under section 501(f)(1)(B) of the Act because it is a class III device under section 513(f) of the Act and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) or an approved application for an investigational device exemption under section 520(g).

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In addition, your device is misbranded under section 502(o) of the Act because you have not submitted a section 510(k) premarket notification to the agency of your intent to introduce the device into commercial distribution. For a device requiring premarket approval, the notification required by section 510(k) of the Act is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b).

The kind of information you need to submit in order to obtain marketing clearance is available through the Internet at <http://www.fda.gov/cdrh/devadvice/3122.html>. The FDA will evaluate this information and decide whether your product may be legally marketed.

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

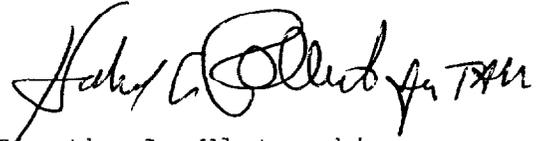
You should take prompt action to correct this serious violation. Failure to act promptly may result in regulatory action being initiated against you by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violation, including an explanation of each step being 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.

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Your response should be sent to Tanisha A. Anthony, Consumer Safety Officer HFZ-331, Food and Drug Administration, 2094 Gaither Road, Rockville, MD 20850. If you have any questions regarding this letter, please contact Ms. Anthony at (301)594-4613.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is fluid and cursive, with a large initial "T" and "U".

Timothy A. Ulatowski  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health