



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

July 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jason R. Zinn, President
Feel Good For Life, Inc.
10311 W. Hampden Avenue, Suite A-108
Lakewood, Colorado 80227

DEN-01- 43

Dear Mr. Zinn:

We are writing to you because on October 16, 2000, and January 5, 2001, Investigator Patricia Cortez, from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving your magnetic products, such as your neck wrap, love magnet, and magnetic headband, which are marketed by your firm, and the claims made for magnetic therapy in literature distributed by your firm.

Under United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices ensure that the products they market are labeled correctly and adequately.

Because you do not have marketing clearance from FDA, your magnetic therapy devices are in violation of the law. In legal terms, your products are misbranded under section 502(o) and are adulterated under section 501(f)(1)(B) of the Act. Your devices are misbranded because you did not submit premarket notification submissions, as required by section 510(k). Your devices are adulterated because you do not have approved applications for premarket approval in effect under section 515(a) or approved applications for investigational device exemption under section 520(g) of the Act. These approvals are required unless you have submitted premarket notification submissions that show that your devices are substantially equivalent to other devices that are legally

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marketed and have been notified by FDA that you may market your magnetic therapy devices.

FDA is not aware of any information to support the numerous claims that you are making for your products. This is to inform you that your devices are also misbranded under section 502(a) of the Act, if the labeling represents or suggests that your devices can be used for diseases or conditions for which magnets are not both safe and effective, if it includes claims regarding purported modes of action or effects on the body that are false or misleading, or if it is false or misleading in any other way. Your devices are also misbranded under section 502(f) of the Act if their labeling fails to bear adequate directions for the safe and effective treatment of all of the conditions for which they are labeled or promoted, including all of the conditions found on your firm's website, www.feelgoodfast.com.

Our review of this website reveals that you are promoting your magnetic therapy devices for numerous diseases and conditions, including cancer, viral infections, bacterial infections, parasites, heart disease, broken bones, severe burns, cuts, ulcers, diabetic peripheral neuropathy, fibromyalgia, phlebitis (blood clot), bronchitis, menstrual cramps, carpal tunnel syndrome, arthritis, degenerative joint conditions, allergies, obesity, high blood pressure, habitual headache, multiple sclerosis, cerebral palsy, polio, post-polio syndrome, and "all the other crippling and killer diseases known to man." Your website also suggests many purported modes of action and effects that magnets have on the body, such as speeding wound healing, improving circulation, changing the migration of calcium ions, altering pH, enzyme activity, and hormone production, enhancement of the lymphatic system, affecting pain receptors, and untrapping trapped blood proteins.

Our records also show that the agency has informed you previously that these types of claims are unacceptable. This is a serious violation of the law, which may result in FDA taking regulatory action without further notice to you. Regulatory sanctions we have available include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your products, or assessing civil money penalties. FDA may assess civil money penalties against you, individually, and against FeelGood For Life, Inc., for violations of section 301(a) of the Act, i.e., the introduction or delivery for introduction into interstate commerce of any...device...that is adulterated or misbranded. Under Section 303(f)(1)(A) of the Act, FDA may impose civil money penalties of up to \$15,000 on you as an individual, and a like amount on FeelGood For Life, Inc., for each violation of a requirement of the Act, up to a total of \$1,000,000 per respondent for all violations. In this case, a violation of Section 301(a) occurs each and every time FeelGood For Life Inc. ships a magnetic therapy device.

In addition to the Federal Food, Drug, and Cosmetic Act, you may also be subject to the provisions of the Federal Trade Commission Act, which prohibit deceptive acts or practices in or affecting commerce, and the dissemination of any false advertisement to

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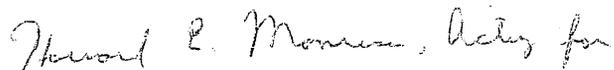
induce the purchase of a food, drug, or device. (See Sections 52 and 45 of Title 15 of the United States Code.)

It is necessary for you to take action on this matter now. Please let this office know, in writing, within fifteen (15) working days from the date you receive this letter as to the steps you are taking to correct the problem. We request that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Shelly L. Maifarth, Compliance Officer, at the address above.

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 labeling for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Ms. Maifarth at (303) 236-3046.

Sincerely,



Thomas A. Allison
District Director

Mr. James Matuszewski, CEO

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