



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

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CERTIFIED - RETURN RECEIPT REQUESTED

REF: #KAN98-024

September 16, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Dr. C. Norman Shealy
Self-Health Systems
5607 S. 222nd Road
Fair Grove, MO 65684

Dear Dr. Shealy:

On May 1, 1998, an Investigator from the Kansas City District Office of the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the Shealy RelaxMate Glasses which is marketed by your firm. Under the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body.

During the inspection conducted on May 1, 1998, you stated the Shealy RelaxMate Glasses are undergoing clinical research to gather data to support a claim of "tension reduction," and that Quantum IRB, Springfield, Missouri found these glasses to be a non-significant risk device. A non-significant risk (NSR) study is subject to all of the abbreviated requirements described in Title 21 Code of Federal Regulations, Section 812.2(b) [21 CFR 812.2(b)], Investigational Device Exemption (IDE) regulation. The abbreviated requirements stipulate the sponsor of the investigation must label the device in accordance with 21 CFR 812.5; obtain institutional review board (IRB) approval of the investigation as an NSR study; ensure that each investigator obtains informed consent from each subject under the investigator's care; comply with the monitoring requirements of 21 CFR 812.46; maintain records required under 21 CFR 812.140(b)(4) and (5) and file the reports required under 21 CFR 812.150(b)(1) through (3) and (5) through (10); and ensure participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and file the reports required under 21 CFR 812.150(a)(1), (2), (5) and (7).

Under the abbreviated IDE requirements, a sponsor must also comply with the prohibitions against promotion and other practices as identified in 21 CFR 812.7. According to this section of the regulation, the sponsor of an NSR study, investigator or any person acting for or on behalf of the sponsor or investigator is prohibited: from promoting or test marketing the investigational device until after FDA has approved the device for commercial distribution; commercializing the device by charging a price greater than that necessary to recover the cost of manufacture, research, development, and handling; unduly prolonging the investigation; and representing the investigational device as safe or effective for the purposes for which it is being investigated.

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Our review of "The Shealy RelaxMate Instruction Manual" determined the statement "CAUTION - Investigational device. Limited by Federal (or United States) law to investigational use, " is not included as required by 21 CFR 812.5(a) . Furthermore this manual indicates the device is safe and effective for the purposes for which it is being investigated. For example the manual states:

"Reduce Tension Quickly"

"Ninety percent of individuals report feelings of deep relaxation and reduced tension within 10 minutes of experiencing The Shealy RelaxMate. Deep relaxation lowers adrenaline production and insulin requirement. We recommend you use the RelaxMate 15 minutes twice a day plus one hour as you de-tense for sleep at night."

"The Ten-Minute Stress Reducer"

"Conservatively, I believe this is the greatest stress reducer I've experienced. Remember the relaxation response is the antidote to stress. The Shealy RelaxMate is the first major breakthrough in a practical relaxation response device. You don't have to do anything. The RelaxMate does it for you!"

"For hundreds of years, scientists and researchers have known that when a person gazes at flashing or flickering lights, it can bring about a calm and relaxed state of being."

"Different levels of relaxation are measured in terms of 'ALPHA' and 'THETA.'"

"At the ALPHA level of relaxation, you experience calmness/tranquility. Sustained relaxation at this level can increase energy and alertness."

"THETA relaxation is experienced when you are deeply relaxed, usually just before falling asleep. Concentration, intuition and creativity can be enhanced in the THETA level."

"The Shealy RelaxMate will guide you into the ALPHA and THETA levels of relaxation, where you can experience the benefits of relaxation and prepare for a good night's sleep."

"SHEALY RELAXMATE FREQUENCIES/USAGE"

"THETA 2-7.4hz"

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“Profound relaxation for relief from deep sources of stress. Use when you want to spend a truly quiet, non-active evening. Prepares you for a full night of quality sleep.”

“ALPHA 7.5-12hz”

“Relaxation that leaves you alert, refreshed and ready to go about your business. Ideal to help you unwind after a hectic day and prepare to enjoy the evening activities. You may try the Alpha setting in the morning so you can start your day calm and refreshed. Use for 15 minutes.”

Such statements are prohibited under 21 CFR 812.5(b) and 812.7(a).

Your investigation is not considered to have an approved application for an IDE because you have not complied with the requirements of 21 CFR 812.2(b). FDA is concerned your investigation may be a significant risk investigation due to the possibility use of the device may cause seizures in susceptible individuals. You must provide data or information demonstrating the device is not a significant risk device and a copy of the IRB approval you have obtained.

Manufacturers of medical devices who do not have an approved IDE must obtain marketing clearance for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring 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 you obtained marketing clearance before you began offering your product for sale.

Since you do not have marketing clearance from FDA, marketing your product is a violation of the law. Specifically, the product is adulterated under section 501(f)(1)(B) and misbranded under 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you showing you device is safe and effective. Your product is misbranded under the Act because you did not submit information showing your device is substantially equivalent to other devices that are legally marketed.

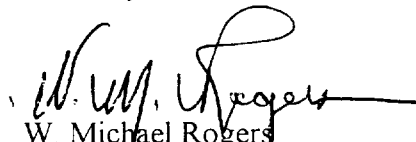
FDA considers this a serious violation of the law and may result in additional regulatory action without further notice to you. These actions include, but are not limited to, seizure of your product inventory, obtaining a court injunction prohibiting further marketing of your product or assessing civil money penalties. Additionally, other Federal agencies are informed about the warning letters we issue so they may consider this information when awarding government contracts.

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We request you respond to this letter, in writing, within ten (10) working days of receipt, detailing steps you will take in regards to these violations as they pertain to your product. Additionally, please advise us of any action you have taken or plan to take with regard to Shealy RelaxMate glasses that you have previously distributed.

Please direct your response to Ralph J. Gray, Compliance Officer at the above listed address.

Sincerely,


W. Michael Rogers
District Director
Kansas City District Office