



JUL 14 2004

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

WARNING LETTER

VIA FEDERAL EXPRESS

Gilberto Jacobo, Jr.
Expanded Vision
236 E. 3rd Street, Unit "A"
Perris, California 92570

Dear Mr. Jacobo:

We are writing to you because a review of your web sites <http://www.expandedvision.com>, <http://www.colonboards.homestead.com>, and <http://www.365totalcolonhealth.com>, revealed a serious regulatory problem involving the products known as the "Colon Board," "Colon Cleansing Board Pail Assembly," "Colon Cleansing Insert Tips," and "Colon Cleansing Board Kit," which are marketed by your firm.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (the 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 of man. The law generally requires that manufacturers of medical devices obtain marketing 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.

According to your web sites, the Colon Board, Colon Cleansing Board Pail Assembly, Colon Cleansing Insert Tips, and Colon Cleansing Board Kit are a "Complete System of Colon Cleansing," used for the purpose of home colon cleansing (set-up in the bathroom) and colonic irrigation. From the design, the device appears to be an enema kit, a Class I device "intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon." 21 CFR 876.5210. However, the intended uses of the device resemble those for a colonic irrigation system (21 CFR 876.5220(b)(2)), a Class III prescription device. Examples of these claims include that a toxic colon is a major factor in the development of food intolerance leading to chronic ill health, colon cleansing is the first step on the road to recovery, and it restores the balance of the good and bad bacteria. Based on these claims, your device cannot be considered an "enema kit" under FDA's regulation and may not be marketed without clearance from FDA.

Our records do not show that you obtained marketing clearance or approval before you began offering your products for sale. The kind of information you need to submit in order to obtain this clearance or approval is described on FDA's device web site at www.fda.gov/cdrh/devadvice. FDA will evaluate this information and decide whether your products may be legally marketed.

Because you do not have approval or marketing clearance from the FDA, marketing your products is a violation of the law. In legal terms, the products are adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your products are misbranded under the Act because you did not submit section 510(k) premarket notifications that show your devices are substantially equivalent to other devices that are legally marketed. Until you submit section 510(k) premarket notifications and FDA reviews them and notifies you that you may market your devices, your products are also adulterated under the Act because the law requires, and you do not have, approved premarket approval applications that show your devices are safe and effective. For a product requiring premarket approval, the notification required by section 510(k) of the Act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).

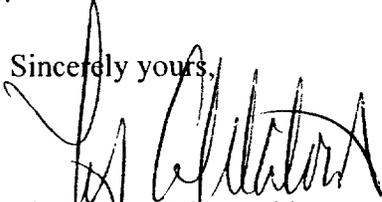
Your Colon Board, Colon Cleansing Board Pail Assembly, Colon Cleansing Insert Tips, and Cleansing Board Kit are also misbranded under section 502(o) of the Act, in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 and were not included in a list required by section 510(j).

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask 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 Mr. Paul Tilton, Chief, OB/Gyn, Gastroenterology and Urology Devices Branch (HFZ-332), Division of Enforcement A, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Road, Rockville, Maryland 20850.

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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter does not necessarily address all of the obligations you have under the law.

Sincerely yours,


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