U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Inspections, Compliance, Enforcement, and Criminal Investigations

M&A Caribbean Traders, Inc 3/28/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos
San Juan, Puerto Rico 00901-3223
Telephone: 787-729-8500
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WARNING LETTER
14-SJN-WL-03

March 28, 2014

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Martin Aguilar, President
M&A Caribbean Traders, Inc.
P.O. Box 363
Cabo Rojo, PR 00623

Dear Mr. Aguilar:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.MegaGraviola.com in March 2014, and has determined that you are promoting the product, MegaGraviola, for conditions that cause the product to be a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA's regulations through links on FDA's homepage at www.fda.gov[1].

Examples of some of the claims on your website www.MegaGraviola.com that provide evidence that your product is intended for use as a drug include:

On the home page titled "MegaGraviola.com":

- "[L]lowers blood pressure…anti-bacterial?"
- "Scientists…discovered its ability to kill malignant cells of 12 different types of cancer, including ovarian, colon, breast, prostate, lung, liver, cervical, lymphoma, and pancreatic cancer. Laboratory research showed it to be 10,000 times stronger in killing colon cancer cells than Adriamycin, a commonly used drug. And Graviola, unlike chemotherapy, can kill cancer cells withou harming healthy cells."
- "Graviola has been used Traditionlly [sic] for centuries by local Natives for…Fever, Flu…Skin Disease…Diarrhea, Dyspepsia…"

On the webpage titled "Graviola Extract":

- "Supports a decrease in blood pressure"
- "Prevents abnormal cell growth that may lead to cancer"
- "Other historic uses for graviola include treatment of influenza, herpes, rheumatism, diarrhea… scurvy, asthma, fever, diabetes…arthritis…dysentery, ulcers, ringworm, malaria…insomnia…and liver problems. Use of graviola for the treatment of bacterial and fungal infections is common."
- "The alkaloids contained in graviola have been tested and found to exhibit positive antidepressant results, increasing the amounts of neurotransmitters, norepinephrine, and dopamine."
- "Used as an astringent, graviola treats dysentery and diarrhea."

On the webpage titled "Graviola & Cancer":

- "Another experiment was conducted by Purdue University's School of Pharmacy and Pharmacal [sic] Sciences in 1998, which confirmed findings in which two of the compounds showed what scientist[s] refer to as 'significant' anti-cancer activities against 6 human cancer cells, including prostate and pancreatic cancers. The leaves of the plant were successful in destroying malignant cancer cells. Perdue [sic] University's examinations on cancer cells of prostate, pancreas and lungs have all shown outstanding results as well."
- "Catholic University in South Korea has exposed that the active ingredients have ´selective cytoxicity [sic]´ comparable with Adriamycin, a drug that in the past that has been used for breast and colon cancer."
- "[G]raviola relieves depression, kills viruses, reduces fevers, expels worms…stops convulsions."

On the webpage titled "FAQs":

- "**If I have thyroid problems, such as thyroid nodules, may I consume the product?** Yes you can take it, as it is effective in tumor and/or nodules, reducing its size."
- "**Can I use MegaGraviola with Endometriosis?** For this PTC is ideal, because it will improve the endometrium, increasing the vasodilatation, thereby reducing your pain and inflammation."

Your website also contains evidence of intended use in the form of personal testimonials recommending or describing the use of Graviola Extract for the cure, mitigation, treatment or prevention of disease. Examples of such testimonials include:

On the webpage titled "Testimonials":

- "20 malignant tumors disappear -- in less than two months...I immediately started myself on a rigorous program of supplements, including Graviola…Within two months, my PSA [Prostate-Specific Antigen] levels plummeted from a dangerous 4.1 to a perfectly normal 0.00.And sonogram and gamma-ray tests showed that every prostate tumor had completely disappeared!"
- "My husband has just been diagnosed with cancer…my husband has been taking the Graviola Extract for a few weeks and it helps him to feel much better after his chemotherapy and radiation treatments."

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]; see also section 301(d) of the Act [21 U.S.C. § 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, your product MegaGraviola is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, this drug is misbranded within the meaning of section 502(f)(1) of the Act, in that its labeling fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including seizure and/or injunction.

Please notify this office in writing within 15 working days from your receipt of this letter as to the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete all corrections within 15 working days, please explain the reason for the delay and the date by which each such item will be corrected.

Please send your written response to the attention of Mr. Carlos A. Medina, Compliance Officer, Food and Drug Administration, San Juan District Office. If you have any questions regarding this letter, please contact Carlos A. Medina at (787) 729-8617 or via email at carlosa.medina@fda.hhs.gov.

Sincerely,
/s/
Maridalia Torres
District Director
San Juan District

Page Last Updated: 05/23/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.fda.gov/