

**U.S. Food and Drug Administration**Protecting and Promoting *Your* Health[Home](#) [Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Compliance Actions and Activities](#) [Warning Letters](#)**Inspections, Compliance, Enforcement, and Criminal Investigations****Graviola Group 4/2/14**

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Juan District
Compliance Branch
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San Juan, Puerto Rico 00901-3223
Telephone: 787-729-8500
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**CYBER WARNING LETTER
14-SJN-WL-04****April 2, 2014****CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Edwin Cardona
Graviola Group
375 Arboles de Montehiedra St
San Juan, PR 00926

Dear Mr. Cardona:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.graviolagroup.com in February 2014, and has determined that you take orders there for the product, Graviola Extract, which the website promotes 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.gov¹.

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

On the webpage titled "Graviola Extract" under the Benefits tab:

- "Graviola extract is the best alternative supplement to support the cancer tratments [sic] and to help with the cure of the following types of cancer: **Prostate cancer, (Also help with the Prostatitis) Breast cancer Lung cancer Colon cancer, (Rectume [sic] Cancer) Uterus Cancer Non-Hodgkin Melanoma Skin cancer Kidney Cancer Ovary Cancer**"

On the webpage titled "Graviola Extract Benefits" under the Benefits tab:

- "It is [sic] been considered as a natural Chemotherapy."

- "Kills cancer cells without harming healthy cells."
- "Effective in treating cancer, especially breast, pancreas, colon, prostate, lung and liver."
- "Prevents the growth of malignant tumors."

On the webpage titled "Is Graviola a Cancer Cure?" under the Benefits tab:

- "Scientific studies at Purdue University in Indiana, USA and Japan, have demonstrated exceptional benefits for the treatment of certain types of cancerous tumors especially those located in the lung, pancreas and prostate."
- "Contains powerful active anticancer ingredients or cytostatic and Acetogenins that Graviola leaf contain. Comparative studies were done in vitro by comparing the effect with adriamycin (known chemotherapy). It was found that is 10,000 times more powerful, and that kills cancer cells without harming healthy cells as with chemotherapy (chemotherapy causes nausea, weight loss and hair)..."
- "It is the best alternative when you cannot use the surgery, Cobalt Therapy, Radium Therapy or when you have to stop chemotherapy for it [sic] action and iatrogenic (side effects) on the liver and kidneys."
- "Researches continued in the National Cancer Institute verifying its effectiveness in OF COLON CANCER and PROSTATE. The National Health Center also uses it for other type of cancers (stomach, kidneys and breasts). The Faculty of Medical Sciences of the Catholic University of Korea performed comparative studies with adriamycin (chemotherapy) in the treatment of lung cancer."
- "Graviola, besides being to helps in lung cancer treatments, liver, colon, pancreas, kidney and stomach, it is also antibacterial, antiparasitic...febrifuge...It is also traditionally used to combat...depression...In other countries besides the anticancer action it has different ancient uses: in Brazil (analgesic, antirheumatic and antifebrile). In Haiti (...flu...)...Panama (...allergies). Venezuela (Liver disease). Malaysia (rheumatic...).
- **"Recommended uses:** Antitumor Anticarcinogenic...Fight Asthma Fight Hypertension Fight Diabetes Corrects liver disorders Action Properties: antibacterial, anticancer, antiparasitic, antitumor...cytotoxicity, febrifuge...vermifuge."

On the website titled "Cancer and Chemotherapy" under the Benefits tab:

- "The Graviola extract helps with the chemotherapy since it is a complement to kill the cancer infected cells with no harm to the other good cells."

Your website provides links from your testimonials tab to videos that contain 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 video titled "Noelia / Endometrial Cancer and Breast Cancer" on your website, accessible at: <http://www.youtube.com/watch?v=Ye1o4W7hC1s>, the testimonial states,

"[I] was diagnosed with endometrial cancer...After six months I was diagnosed with breast cancer with carcinogenesis on the left breast and proliferated cells in the right breast...In my desperation of looking for a cure for those secondary effects that the chemotherapy and the treatment of the five years of the pill that I was using I found Graviola Extract of Puerto Rico. Immediately I started to use it...In my visits to the doctors, they said to Noelia your [sic] perfect, you are okay." (0:15 – 1:26)

On the video titled "Irma / Irritable Colon Syndrome" on your website, accessible at: <http://www.youtube.com/watch?v=N-YtRr5hw4E>, the testimonial states,

"[I] was diagnosed [with] Irritable Colon [bowel] Syndrome for more than four years with liquid evacuations all the time...I can used [sic] it because it [sic] going to do me good. I started to use the Graviola and a half-week later I noticed that I could go out because I didn't have liquid retraction. I feel better and my hypertension was low..." (0:11 – 0:48)

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 Graviola Extract 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 fifteen (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

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U.S. Department of **Health & Human Services**

Links on this page:

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