



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Southwest Region

Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087

September 20, 2006

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Gary Hollister
Chief Executive Officer
Xango LLC, International
3098 Executive Parkway
Lehi, Utah 84043

Ref # - DEN-06-22

Dear Mr. Hollister :

This letter is to advise you of serious concerns that the Food and Drug Administration (FDA) has regarding the promotion of Xango, your mangosteen-juice product. Labeling used by distributors of your product promotes your product for use in the cure, mitigation, treatment, or prevention of disease. Products intended for such uses are drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)(1)(B)].

FDA obtained brochures promoting the health benefits of mangosteens and mangosteen juice through contact information provided at a seminar at which representatives of your firm, David and Joe Morton, made presentations designed to recruit distributors for Xango. By using a telephone number provided by staff at the seminar, FDA ordered the "Mangosteen Brochure Combo Pack." FDA subsequently received a packet of brochures that included ten copies each of nine different brochures promoting the health benefits of mangosteens and mangosteen juice. The packet also included brochures aimed at recruiting distributors for your product.

Under the Act, "labeling" is not limited to labels on the immediate container for your product. "Labeling" is defined in section 201(m) the Act [21 U.S.C. 321(m)] as "all labels and other written, printed or graphic matter upon any article . . . or accompanying such

article." The brochures we received as a prospective distributor of your product meet the definition of "labeling" in section 201(m) of the Act.

Examples of some of the claims in the brochures include:

From "Tame the Flame"

- "For several decades, relief from inflammation has been available through nonsteroidal anti-inflammatory drugs (NSAIDS) like aspirin and ibuprofen. Mangosteen is just that - a proven, natural COX 2 inhibitor."
- One study showed mangosteen extract was a more potent anti-inflammatory agent than several prescription anti-inflammatory medications currently used for arthritis and gout."

From "22 Reasons to Drink Mangosteen Juice"

- "Prevents hardening of the arteries (atherosclerosis)"
- "Anti-inflammatory-Significantly reduces inflammation in the body targeting neck, back, and knee pain. Proven to significantly reduce nerve pain as well."
- "Anti-Parkinson, Anti-Alzheimer and other forms of dementia"
- "Anti-depressant."
- "Prevents bacterial infections (Anti-bacterial)"
- "Prevents and arrests fungus (Anti-fungal)"
- "Viral fighters and prevention of infections (Antiviral). Mangosteen has been used for centuries to treat skin disorders such as dermatitis, infections from wounds, ringworm, acne, and so forth."
- "Prevents gum disease (Antiperiodontic)"
- "Lowers fevers (Anti-pyretic)"
- "Eye care - prevents glaucoma and cataracts (Anti-glaucomic and Anti-cataract)"
- "Weight Loss - helps and prevents obesity (anti-obesity)"
- "Lowers blood fat (Anti-lipidemic) Dr. Templeman says, ". . .the degree of the lowering of LDL equals or exceeds that obtained with some commercial drug preparations . . without the serious side effects of the anti-cholesterol drugs."
- "Anti-Tumor benefits"
- "Cancer: Mangosteen helps in the prevention of cancer with its powerful anti-oxidants . Six Xanthones according to a preliminary study were capable of killing cancer cells."
- "Lowers blood pressure"
- "Blood sugar lowering"

From "An Introduction to Xanthones" -

- "The thick mangosteen rind is used for treating . . .cystitis (inflammation of the urinary bladder), dysentery, eczema (a skin disease), fever. . . ."
- Teas of the mangosteen bark are known for treating genital and urinary infections as well as stomatitis (inflammation of the mouth)."

- "anti-inflammatory"
- "anti-microbial"
- "anti-fungal"
- "anti-viral"
- "anti-cancer"
- "anti-tumor"
- "anti-ulcer"
- "anti-hepatotoxic"
- "Is anti-rhinoviral"
- "anti-allergic"
- "In addition, the anti-inflammatory activities of natural xanthenes found in the mangosteen plant are significant. In particular, one recent study confirmed that gamma mangostin, a xanthone derivative, is a potent COX inhibitor. Suppressing the cellular production of cyclooxygenase, or "COX," is an important factor in reducing inflammation, pain and fever."

From "Mangosteen and the Hormone Balancing Act" -

- "Another way mangosteen keeps the cells and glands of the endocrine system working properly is by fighting off infection."
- "Scientific investigation has shown that mangosteen has strong antimicrobial properties. Anti means against; microorganisms are tiny organisms like bacteria, viruses, yeasts, and molds. Studies report mangosteen stops the growth of Staphylococcus, common bacteria that causes infections if not controlled. Another study done in Thailand found that a mangosteen extract stimulated the phagocytic cells to kill the bacteria Salmonella enteritidis. Other research shows mangosteen to be effective in stopping various types of fungal growth."
- "By drinking mangosteen, you may help prevent infections"

From "Xanthenes and the Chiropractic Connection" -

- "Because of the amazing results I have had with XanGo, I am now drug free and virtually pain free for the first time in 21 years. The .research I have performed on this product has led me to believe that it helps restore liver function, breaks down insulin resistance, and can turn around chronic conditions of inflammation in the cells of the body."
- "Its delicious taste and medicinal qualities not only put dessert on the table but keep the people free of such ailments as dysentery, infections, inflammation, diabetes, and pain, to mention a few."

From "Why Healthy People Drink Mangosteen Juice" -

- "Traditionally, mangosteen was used to help with ailments such as diarrhea, eczema, thrush, urinary infections Currently, many people use mangosteen to help prevent disease by lowering their risk factors for disease"

- "The xanthenes in mangosteen have been shown to inhibit both bacteria (including strains of the staphylococcus bacteria that were antibiotic resistant) and viruses (such as HIV-1). In two separate studies, researchers proved that the xanthenes in mangosteen prevented the growth of as many as six different dangerous fungi."
- "Polysaccharides are incredibly potent anti-cancer and anti-bacterial plant compounds Japanese scientists isolated several polysaccharides from mangosteen that helped decrease murine tumors (a cancerous tumor in mice)."
- "Another study that looked at the polysaccharides from mangosteen found that they were effective against intracellular bacteria (such as Salmonella enteritidis) . The study results showed that the mangosteen's potent polysaccharides killed all of the bacteria in the culture."

From "The Xanthone Effect" - David A. Morton, Ph.D -

- "Science supports the idea that xanthenes found in the mangosteen fruit are an effective remedy for diarrhea and dysentery, mainly by inhibiting the action of the COX-2 enzyme (mechanism of action)."
- "They discovered that some mangosteen xanthenes had been reported, 'to produce analgesic and anticonvulsant effects.' They also stated that the mangosteen xanthenes were 'found to produce significant anti-inflammatory effects.' An interesting sidenote is that some mangosteen xanthenes did not 'cause aggravation of gastric ulcers . . . mangostin produces significant antiulcer activity in experimental animals."
- "They concluded that, 'gamma-mangostin serves not only as a new attractive pharmacological tool for studying the molecular mechanism underlying inflammation but also as a new lead compound for drug development for the prevention and/or treatment of inflammation and brain diseases."

From "Mangosteen [and IBS, and Constipation] An Abdominal Surgeon's Perspective" -

- "Two of the conditions that I have found the mangosteen useful in treating are constipation, and IBS (irritable bowel syndrome), which I will deal with in this brochure."
- "Supplementing with mangosteen should enable you to reduce or eliminate the use of steroids in your treatment. . ."

These claims cause your product to be a drug, as defined in Section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)] . Because this product is not generally recognized as safe and effective when used as labeled, it is also a new drug as defined in Section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the United States without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)] . FDA approves new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are safe and effective.

The introduction or delivery for introduction into interstate commerce of an unapproved new drug is prohibited under the FD&C Act [21 U.S.C. 331(d)] and may lead to enforcement action, including seizure and/or injunction. Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to prevent your distributors from promoting your product in a manner that violates the Act. Your reply should be directed to the attention of Regina Barrell, Compliance Officer, Food and Drug Administration, at the address shown on the letterhead above.

Sincerely,

/s/

B. Belinda Collins
District Director

This page was posted on October 2, 2006.