



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-07

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

October 17, 2005

Mr. Robert Underwood
Flavonoid Sciences
965 Cherry Ridge Dr.
P.O. Box 5017
Traverse City, MI 49696

Dear Mr. Underwood:

The Food and Drug Administration (FDA) has reviewed the labeling, including your web site at www.flavonoidsciences.com, for your CherryFlex and Wild BlueBerry IQ products. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of these products. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease are drugs [Section 201(g)(1)(B) of the Act, 21 USC 321(g)(1)(B)]. The labeling for your products bears the following claims:

Cherry Flex

“Thousands rely on the antioxidant power of red tart cherries for: Arthritis Gout Joint Inflammation Cancer prevention Fibromyalgia Syndrome Heart disease”

“Recent studies show the antioxidant compounds in cherries may be 10 times stronger than Aspirin or Ibuprofen in relieving arthritic pain.”

“Cancer-Fighter Perillyl Alcohol Found in Tart Cherries

[T]art cherries contain perillyl alcohol (POH), a natural compound that is extremely powerful in reducing the incidence of all types of cancer. Perillyl alcohol ‘shuts down the growth of cancer cells by depriving them of the proteins they need to grow,’ explains Dr. Hohl. ‘It works on every kind of cancer we’ve tested it against.’ Perillyl alcohol (POH) has performed favorably in the treatment of advanced carcinomas of the breast, prostate and ovary. POH also has exhibited chemopreventive activity in pre-clinical breast cancer tests. Perillyl alcohol has been shown to induce the regression of 81 percent of small breast cancers and up to 75 percent of advanced breast cancers in animal studies. Perillyl alcohol was up to five times more potent than the other known cancer-reducing compounds at inducing tumor regression.”

“Independent Lab Verifies Cancer-Fighting Agents in Cherries

[D]ocumented the presence of ellagic acid in cherries. Ellagic acid is a naturally occurring phenolic that is known as a potent anti-carcinogenic/anti-mutagenic compound. Clinical tests ... show that ellagic acid may be the most potent way to prevent cancer. It also may inhibit the growth of cancer cells, and arrest the growth of cancer in subjects with a predisposition for the disease.”

Wild BlueBerry IQ

“Wild Blueberry IQ is ... packed with high levels of anthocyanins, a natural antioxidant, believed to be effective in fighting disease...”

“The health benefits of wild blueberries may help:

- Prevent heart disease and stroke
- Guard against Alzheimer’s and other neurological diseases”

“Alzheimer’s researchers excited by Blueberry findings

[B]lueberries reduce ‘aging-related damage in rat brains and can also prevent mental decline in mice genetically engineered to develop Alzheimer’s-like plaques in their brains.’ Conditions such as Alzheimer’s Disease, cancer and heart disease have been linked to oxidative cell damage caused by free radicals, a by-product of normal metabolism. Antioxidants can help prevent this damage – and blueberries lead other fruits and vegetables in antioxidant capacity.”

Your website also includes claims in the form of testimonials. Some examples include:

“I have had the opportunity to offer CherryFlex to my patients for approximately 3 months. I have found it a very effective tool with patients that complain of chronic joint pain and/or stiffness often associated with osteoarthritis or other degenerative processes.”

“I have ordered and used your product, and I must say that nothing else I’ve tried (prescribed or otherwise) has done as much for controlling my Fibromyalgia.”

“I have suffered the pain of Rheumatoid Arthritis and Lupus for years and am no longer able to take anti-inflammatory medication due to kidney damage. My rheumatologist in Lansing recommended your product. It works great!”

“I have suffered from urinary tract infections for years, treating them with prescription drugs. I’ve been taking two BlueberryIQ softgels every day for two years and have not had one infection ever since.”

This list of claims is not intended to be all-inclusive, but represents the types of claims found in your product labeling.

These claims cause your products to be drugs, as defined in section 201(g)(1)(B) of the Act, because they establish that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act (21 USC 355), a new drug may not be legally marketed in the United States

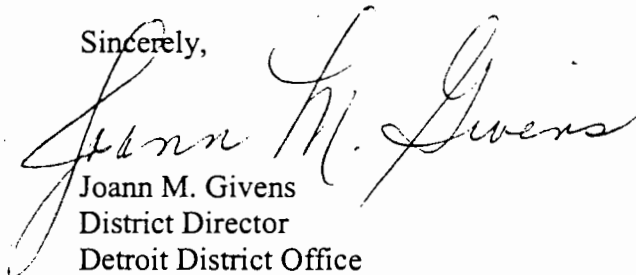
without an approved New Drug Application (NDA). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

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 products marketed by your firm comply with the Act and its implementing regulations.

Failure to promptly correct these violations may result in enforcement action without further notice. Enforcement action may include seizure of violative products, injunction against the manufacturers and distributors of violative products, and criminal sanctions against persons responsible for causing violations of the Act.

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 correct these violations, including the steps taken to assure that similar violations do not recur. Your reply should be directed to Judith A. Putz, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in cursive script that reads "Joann M. Givens". The signature is written in black ink and is positioned above the printed name and title of the signatory.

Joann M. Givens
District Director
Detroit District Office