DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2006-DT-14

October 17, 2005

Hans Neuroth
Obstbaum Orchards
9252 Currie
Salem, MI 48167

Dear Mr. Neuroth:

The Food and Drug Administration (FDA) has reviewed the labeling of your Cherry Juice Concentrate on your web site at www.obstbaum.com as it appeared on August 15, 2005. Our review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of this product. 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 in man are drugs [Section 201(g)(1)(B) of the Act, 21 USC 321(g)(1)(B)]. The labeling for your product on your web site bears the following claims:

> "Benefits: ... anthocyanins and antioxidants in tart cherries are ten times stronger than aspirin or ibuprofen. What this means for your health is that Cherry Juice Concentrate can:
>
> - Reduce the pain of arthritis, gout and headaches
> - Reduce chances of kidney stones, gallbladder ailments and tooth decay ...
> - Cut the risk of heart attack by 30%
> - Lower chances of cancer by as much as 50% through a high amount of Perillyl alcohol that flushes cancer causing substances from the body"

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 product to be a drug, as defined in section 201(g)(1)(B) of the Act [21 USC 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 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 and 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 above address.

Sincerely,

Joann M. Givens
District Director
Detroit District Office