Inspections, Compliance, Enforcement, and Criminal Investigations

Healthtime dba Deer Garden Foods 7/24/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94501-7070
Telephone (510) 337-6700

WARNING LETTER

July 24, 2014

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

Reference: CMS 416769

Mr. Evan J. Richards
Healthtime dba Deer Garden Foods
1570 Shelton Dr. Suite C
Hollister, CA 95023

Dear Mr. Richards:

This is to advise you that the Food and Drug Administration (FDA) conducted a review of your firm's websites, www.rejuvenative.com, www.rawoils.com, www.rejuvenative.com, in June 2014. Our review has determined that your products "100% Organic Evening Primrose Oil," "Spicy Kim-Chi,""Fresh Raw Almond Butter," and "Organic Ginkgo Green Caffeine Tea," may be ordered from these websites. The websites promote these products for conditions that cause the products to be drugs 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 websites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website claims that provide evidence that your products are intended for use as drug include:

On the websites, www.rejuvenative.com and www.rawoils.com:

"100% Organic Evening Primrose Oil" webpage:

- "[U]sed as an anti-inflammatory…"
- "[M]ay also reduce…irritable bowel flare-ups."
- "[L]essen joint pain and reduce swelling caused by rheumatoid arthritis."
- "Prevent and in some cases reverse diabetes-associated nerve damage."

- "Fight damage caused by multiple sclerosis."
- "Reduce the symptoms of eczema."

On the website, www.rejuvenative.com:

"Vegi-Delite Deluxe Zing Salad" webpage:

- "[W]e use cancer-fighting cabbage…anti-bacterial dill, antibiotic lemon…"

"Spicy Kim Chi" webpage:

- "[I]t has been shown to reduce the growth of cancer…"

"Fresh Raw Almond Butter" webpage:

- "Shown to reduce cholesterol and the risk of heart disease"

"Organic Ginkgo Green Caffeine Tea" webpage:

- "[C]an help lower cholesterol…and guard against cancer."

Your products referenced above are not generally recognized as safe and effective for the above referenced uses and, therefore, are new drugs 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, the above-referenced products are 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 these drugs safely for their intended uses. Thus, these drugs are misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], in that their labeling fails to bear adequate directions for use. 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)].

This letter is not meant to be an all-inclusive review of your websites. It is your responsibility to ensure that all of your products are in compliance with the Act and its implementing regulations. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

[B][3]

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct the violations identified above. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the attention:

Lawton W. Lum
Director, Compliance Branch
U.S. Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502

If you have questions regarding any issue in this letter, please contact Brandon Bridgman at (510) 337-6794 or Brandon.Bridgman@fda.hhs.gov.

Sincerely,
/S/
Kathleen M. Lewis, J.D.
Director
San Francisco District

Page Last Updated: 08/07/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.