Healthy Healing dba Crystal Star 8/15/18

Office of Human and Animal Foods - West
Division 1
250 Marquette Avenue, Suite 600
Minneapolis, MN 55401
(612) 334-4100

August 15, 2018

WARNING LETTER

Via UPS Overnight Delivery **Refer to CMS 554500**

Anthony J. Torntore
President
Healthy Healing dba Crystal Star
9821 Valley View Road
Eden Prairie, Minnesota 55344

Dear Mr. Torntore:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your dietary supplement holding and distribution facility located at 9821 Valley View Road, Eden Prairie, Minnesota, on March 29-30 and April 2-3, 2018. As part of the inspection, FDA collected product labeling, including your product catalog, and reviewed your website at the Internet address https://www.healthyhealing.com where you take orders for your Women's Best Friend™ and Para Purge™ products. We determined that claims on your product labels, website and in your catalog establish that these products are 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), 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. You may find the Act and FDA regulations through links on FDA's home page at ***www.fda.gov*** **(http://www.fda.gov/)**.

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

Women's Best Friend™ product

- "[R]educe swelling…" (product label)
- "[T]ake down discomfort and swelling…reduce excess estrogen that fuels abnormal growths…reduc[e] symptoms like abnormal bleeding…" (product label)
- "Goldenseal Root…a supreme anti-microbial…" (sell sheet from your website)
- "Jamaica Dogwood…non-narcotic herbal discomfort relievers… facial nerve discomfort, neuralgia, TMJ, back discomfort, muscle cramps and spasms." (sell sheet from your website)
- "Red Raspberry…helps normalize bleeding." (sell sheet from your website)
- "Protease…helps dissolve abnormal tissue …" (sell sheet from your website)

Para Purge™ product

- "Promotes cleansing and detoxifying the body of foreign organisms" (product label)
- "NEEM LEAF inhibits organism growth…" (product label)
- "Parasite Purge™" (product catalog)
- "Helps cleanse and release a variety of parasitic organisms…prevent reinfestation" (product catalog)
- "Neem Leaf…a broad spectrum vermifuge (destroyer of parasites)…" (sell sheet you provided our investigator)
- "Black walnut hulls…purgative help for intestinal worms…" (sell sheet you provided our investigator)
- "Garlic clove…a vermifuge to help kill and expel worms…" (sell sheet you provided our investigator)
- "Pumpkin seed…a gentle deworming food help, especially for children or pregnant women…" (sell sheet you provided our investigator)
- "Elecampane Root…a bitter herb which helps remove parasites…" (sell sheet you provided our investigator)

Your Women's Best Friend™ and Para Purge™ products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products 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 sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 335(a). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that you comply with all requirements of federal law and FDA 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, without limitation, seizure and injunction.

We take this opportunity to provide the following comment: Our inspection also found violations of FDA's Current Good Manufacturing Practice in the Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements regulation, Title 21, Code of Federal Regulations, Part 111 (21 CFR 111). At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, which listed the violations and these were

discussed with you. We acknowledge receipt of your written responses dated April 11 and May 18, 2018. Your responses indicate that you re-trained employees on receiving, reviewing, and documenting procedures, and have implemented an updated specification review and documentation of products received at your facility. You also indicate that you implemented a new Retention Sample procedure and a new Pest Control procedure. With your second response, you provided a draft manufacturing quality agreement, a pest control SOP and inspection log, and new receiving procedure and release form. Further, you stated that you plan to develop a Supplier Qualification SOP by June 29, 2018. The effectiveness of these corrective actions will be evaluated in a future inspection. In addition, you plan to review and update all labeling and marketing materials by March 31, 2019. Please continue to provide updates with documentation of these corrections as they are made.

Please respond to this office in writing within 15 working days of receiving this letter. In your response, identify the specific steps you have taken or will take to completely correct the current violations and prevent their recurrence. Include the time frame in which the corrections will be completed and provide documentation that will effectively assist us in evaluating whether adequate corrections have been made. If you cannot complete corrective actions within 15 working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration.

Your written response should be sent to Boun M. Xiong, Compliance Officer, at the address in the letterhead. If you have any questions about this letter, please contact Mr. Xiong at (414) 326-3976.

Sincerely,
/S/
Michael Dutcher, DVM
Director, West Division 1
Office of Human and Animal Food Operations

More in Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)