U.S. Food and Drug Administration

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# Dherbs Health Emporium Inc. 12/10/15

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Department of Health and Human Services

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Food and Drug Administration
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**WARNING LETTER**

**UNITED PARCEL SERVICE**
**SIGNATURE REQUIRED**

December 10, 2015

**WL #11-16**

Ahman Dolphin, CEO
Dherbs Health Emporium, Inc.
10755 Venice Blvd.
Los Angeles, CA 90034

Dear Mr. Dolphin:

From June 19 through 24, 2015, the U.S. Food and Drug Administration (FDA or we) inspected your facility located at 10755 Venice Blvd. Los Angeles, CA. Based on our inspection and subsequent review of your product labeling collected during the

inspection, including your firm's website at www.dherbs.com, we found serious violations of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations. You may find the Act and FDA regulations through links on the FDA's home page at www.fda.gov.

We acknowledge receipt of your responses, provided by your counsel via email, dated July 6, 14, and 15, 2015, to the Form FDA 483, Inspectional Observations, issued to you at the conclusion of the inspection on June 24, 2015, and we address your responses below. Please note that the only substantive response was that dated July 14, 2015.

**Unapproved New Drugs and Misbranded New Drugs**

We have reviewed the labeling of your products obtained during the inspection, as well as labeling for products available on your website at www.dherbs.com. We have determined that you take orders for several of your products, to include products available on your online store, as described below. Based on our review, we have determined that your website and other product labeling promote your products for conditions that would cause the products to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The therapeutic claims on your websites and other product labeling 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. You may find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

The following are examples of claims that provide evidence that your products are intended for use as drugs:

10 Day Kidney Cleanse:

- "Helps to soothe and heal genital tract inflammation"
- "Works to minimize kidney stones"

Anti-Viral Cleanse and Regimen

- "[F]ight against viral diseases and infections"
- "Promotes healing of the blood and lymphatic fluid"
- "[S]oothe and heal skin eruption and blisters"

Athletic Package:

- "Works to reduce inflammation …"

Cardiovascular Extract

- “[H]elp your body regulate and stabilize cholesterol levels”

Cough Extract

- “ [S]timulate mild coughing to help clear phlegm”
- “ [R]elief of chronic cough symptoms’
- “ [F]ight infection”

Kidneys Extract

- “ [R]egulate blood pressure and electrolytes”

Vitamin K

- “[P]revent harmful blood clots, arrest internal bleeding, help keep bones strong and healthy, and provide essential nutrients to pregnant women”

Fibroid Cleanse and Regimen

- “[C]orect [sic] iron amenia deficiency”
- “[H]ealing endometriosis”
- “[H]elp with the reduction of fibroids and tumors in the female reproductive system”
- “Eliminate blood clots”

Circulation Aid

- “ [P]revent cardiovascular disease”

Cerebrovascular Formula

- “[R]epair…cerebrovascular system and brain”
- “[P]reventing future strokes … “
- “[H]elping oxygen flow to the brain”

Sex Organs Cleanser

- “[L]essen inflammation of urinary tract and reproductive system”
- “Diuretic effect helps cleanse kidneys of waste and toxins”

Vitamin A

- “[F]ight infections”

Your products identified above 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 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, your 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 the drugs safely for their intended purposes. Thus, these products 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)].

**Adulterated Dietary Supplements**

Even if your products did not have therapeutic claims which make them unapproved new drugs, the products would still be adulterated dietary supplements within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] because the products have been prepared, packed, or held under conditions that do not meet the Current Good Manufacturing Practice (CMGP) regulations for dietary supplements, found in Title 21 of the Code of Federal Regulations, Part 111 (21 CFR Part 111).

During the inspection, investigators observed the following significant violations:

1. You failed to establish product specifications for the identity, purity, strength, composition, and for limits on these types of contamination that may adulterate, for each finished batch of dietary supplements that you manufacture, as required by 21 CFR 111.70(e). Specifically, during the inspection, you were unable to furnish finished product specifications for each product you manufacture. Additionally, once you have established product specifications you must verify that your finished batch of the dietary supplement meets product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or that may lead to adulteration of the finished batch of the dietary supplement, as required by 21 CFR 111.75(c).

We were unable to evaluate the adequacy of your corrective action based on your response dated July 14, 2015 because you have not demonstrated that you are verifying that your finished batches of the dietary supplements meet established product specifications for identity, purity, strength, composition, and for those types of contamination that may adulterate the finished batches.

2. You failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, as required by 21 CFR 111.103. Additionally, once you have established your quality control procedure you must implement quality control in your manufacturing, packaging, labeling, and holding operations, as required by 21 CFR 111.65. Specifically, products received from your contract manufacturer are not reviewed and released by quality control prior to packaging/labeling operations or distribution.

We were unable to evaluate the adequacy of your corrective action based on your response dated July 14, 2015 because you did not provide evidence of the quality control procedure(s) being established and implemented.

3. You failed to establish and follow written procedures for packaging and labeling operations, as required by 21 CFR 111.403. Specifically, on 6/19/15 our investigator observed an employee labeling dietary supplement Blood & Lymphatic, **(b)(4)** with no written procedure to follow.

Additionally, when establishing your procedure, you must ensure that it includes the requirements of assigning a batch, lot, or control number to each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement, as required by 21 CFR 111.111.415(f)(1). Specifically, during the inspection it was observed that you are not consistently assigning unique batch numbers to dietary supplements that you distribute from your facility.

You must make and keep records for all packaging and labeling operations performed on each batch of finished dietary supplement, as required by 21 CFR 111.430(a). Specifically, during the inspection you were asked to provide labeling records for Blood & Lymphatic **(b)(4)** and you were unable to do so.

We were unable to evaluate the adequacy of your corrective action based on your response date July 14, 2015 because you did not provide evidence of packaging and labeling procedure(s) being established and implemented.

4. Your firm failed to establish and follow written procedures for holding and distributing operations, as required by 21 CFR 111.453. You acknowledged that you don’t have written procedures for holding and distributing products. You informed our

investigator that you would work with the contract manufacturer regarding product shipment, storage and return.

We were unable to evaluate the adequacy of your corrective action based on your response dated July 14, 2015 because your response only stated that you would have written procedures implemented in two months; this response does not provide sufficient information for us to evaluate the corrective action that you have taken because you did not provide examples of the procedures or evidence of implementation.

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 your firm complies 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.

Section 743 of the Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees to cover FDA's costs for certain activities, including reinspection-related costs. A reinspection is one or more inspections conducted subsequent to an inspection that identified noncompliance materially related to a food safety requirement of the Act, specifically to determine whether compliance has been achieved. Reinspection-related costs means all expenses, including administrative expenses, incurred in connection with FDA's arranging, conducting, and evaluating the results of the reinspection and assessing and collecting the reinspection fees (21 U.S.C. 379j-31(a)(2)(B)). For a domestic facility, FDA will assess and collect fees for reinspection-related costs from the responsible party for the domestic facility. The inspection noted in this letter identified noncompliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective actions within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your reply should be sent to the following address:

CAPT Daniel Cline, Acting Director
Compliance Branch
U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, CA 92612-2506

If you have questions regarding this letter, please contact Dr. Raymond W. Brullo, Compliance Officer, at 949.608.2918, or via e-mail to raymond.brullo@fda.hhs.gov.

Sincerely,
/S/
LCDR Steven Porter, Acting Director
Los Angeles District

Cc:
David Mazzera, Chief, Food and Drug Branch
California Department of Public Health
1500 Capitol Avenue, MS-7602
P.O. Box 997435
Sacramento, CA 95899-7435
Attn: FDA Correspondence

**More in 2015**

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