U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Better Health Lab, Inc 2/18/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Jersey District Office
Central Region
Waterview Corporate Center
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054
Telephone: (973) 331-4900
FAX: (973) 331-4969

February 18, 2015

VIA UPS OVERNIGHT DELIVERY

Mr. Robert Kim
Owner/Managing Director
Better Health Lab, Inc.
200 South Newman Street, Unit 1
Hackensack, NJ 07601

WARNING LETTER

Warning Letter No.: 15-NWJ-04

Dear Mr. Kim:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm,

Better Health Lab, Inc., located at 200 South Newman Street, Hackensack, NJ from September 10 through September 22, 2014. During the inspection FDA collected labeling for your products. In addition, the FDA subsequently reviewed your websites at www.alkazone.com and www.antioxidantwater.com in November of 2014. A review of your websites determined that you take orders for your ALKAZONE® Alkaline Booster, ALKAZONE® Gout Reliever, and ALKAZONE® Premium Energy Booster products at www.antioxidantwater.com. Your website www.antioxidantwater.com automatically redirects to your website at www.alkazone.com, where your ALKAZONE® Premium Energy Booster product can be purchased. Based on our inspection and subsequent review of your product labeling collected during the inspection, as well as your firm's websites, 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 FDA's home page at **www.fda.gov (http://www.fda.gov)**.

We acknowledge your written response dated September 30, 2014. The agency has reviewed your response as discussed below.

The inspection and our review of your websites and product labeling collected during the inspection revealed the following significant violations:

Unapproved New Drugs

FDA has reviewed your product labels for your ALKAZONE® Alkaline Booster with Antioxidant and ALKAZONE ANTIOXIDANT WATER® products. Further, FDA reviewed your websites at the Internet addresses www.alkazone.com and www.antioxidantwater.com in November 2014 and has determined that you take orders at these websites for the products ALKAZONE® Alkaline Booster with Antioxidant, ALKAZONE Gout Reliever, and ALKAZONE® Premium Energy Booster. Your product labels and websites promote these products for conditions that cause them 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 product labels and 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 the claims found on your product labels and websites that provide evidence that your products are intended for use as drugs include:

ALKAZONE® Alkaline Booster with Antioxidant

- "The acidic load [in a person's stomach] may cause gastric ulcers and other stomach problems. However, ALKAZONE® may neutralize the harmful effects of acid buildup."
- "ALKAZONE® may...redl!ce the side effects of alcohol."
- "Selenium (an ingredient in your product) can prevent cancer growth or reduces the growth rate of certain cancers. Additionally the occurrence of heart disease and severe arthritis was greater in diets that were low in selenium."
- "Help regulate blood pressure."
- "Mitigatethe strain placed on kidneys from excess alcohol."
- "Lessen the unwanted side-effects of medications like Aspirin while not reducing their efficacy."

ALKAZONE ANTIOXIDANT WATER®

- "Potassium [an ingredient in your product]...helps regulate blood pressure..."
- In the "Doctor'sOpinion"video, available at www.alkazone.com/doctors-opinion/
    - "[A]t the end of the day hypertensive patient will get a headache because the body will have less oxygen and less potassium in this particular instance I have seen it enhance that and ameliorate their headaches..."
- "Potassium Enriched-which helps toregulate blood pressure..."
- "[S]cientists have found that this water has a positive effect uponthe health of patients suffering from severe illnesses."

ALKAZONE® Gout Reliever

- "Gout [i]s one of themost painful forms of arthritis. Itoccurs when toomuch uric acid buildsupinthebody.The buildup of uric acid can lead to:
    - Sharp uric acid crystal deposits in joints, often in the big toe.
    - Deposits of uric acid that look like lumps under the skin.
    - Kidney stones from uric acid crystals in the kidneys.
    - Decrease Uric Acid Level."
- "Reduce the side effects of alcohol."

ALKAZONE® Premium Energy Booster

- "Potassium [an ingredient in your product] is a vital element of minerals essential for multiple body fundIons [sic]:
    - Enhances activity of heart muscle to reduce the risk of heart disease
    - Normalizes blood pressure"

- "Zinc and Selenium ElectrolyteMinerals
  - Reduces the risk of heart disease
  - Decreases blood pressure."
- "Zinc [an ingredient in your product] has also been credited to aid in the fight for the resistance against inflammation."

Your ALKAZONE® Alkaline Booster with Antioxidant, ALKAZONE ANTIOXIDANT WATER®, ALKAZONE® Gout Reliever, and ALKAZONE® Premium Energy Booster 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 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 ALKAZONE® Alkaline Booster with Antioxidant, ALKAZONE ANTIOXIDANT WATER®, ALKAZONE® Gout Reliever, and ALKAZONE® Premium Energy Booster are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions cannot be written so that a layperson can use them safely for their intended purposes. Thus, these drugs are misbranded within the meaning of section 502(f)(1) of the Act, in that their labeling fails to bear adequate directions for use [21 U.S.C. §352(f)(1)]. 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 Supplement

Even if your ALKAZONE® Alkaline Booster with Antioxidant product was not an unapproved new drug, it would still be an adulterated dietary supplement under section 402(g)(1) of the Act. The inspection revealed significant violations of the CGMP requirements for dietary supplements. These violations cause your dietary supplement products to be adulterated under section 402(g)(1) of the Act [21 U.S.C.§ 342(g)(1)] in that they have been prepared, packed, or held under conditions which do not meet the Current Good Manufacturing Practice (CGMP) regulations for dietary supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR Part 111).

Specifically, during the inspection, our investigators observed the following significant violations:

1. You failed to establish the following specifications required by 21 CFR 111.70:

a. Identity specifications for each component that you use in the manufacture of a dietary supplement [21 CFR 111.70(b)(1)];
b. Component specifications that are necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met [21 CFR 111.70(b)(2); and
c. Product specifications for each dietary supplement for the identity, purity, strength, and composition of the finished batch of the dietary supplement, 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 [21CFR 111.70(e)]. Specifically, you have only set product specifications for the pH level, aluminum, iron, lead, and mercury for your finished dietary supplement product.

We acknowledge that in your response, dated September 30, 2014, you stated that you "will find out the ways to test or examine the product," as well as examine the components for purity, strength, and composition. Because you failed to include specifications for each of the components you use to manufacture dietary supplements as well as specifications for each finished dietary supplement, we are unable to evaluate the adequacy of your response.

2. Your batch production records failed to include complete information relating to the production and control of each batch as required by 21 CFR111.255(b). Specifically, your batch production records for your ALKAZONE® Alkaline Booster with Antioxidant product were missing the following information:

a. Identification of the filling equipment such as the filling and packaging line used in production as required by 21 CFR111.260(b);
b. The unique identifier that you assigned to each component as required by 21 CFR 111.260(d);
c. A statement of actual yield and a statement of the percentage of the theoretical yield at appropriate phases of processing as required by 21 CFR 111.260(f);
d. The date on which each step of themanufacturing process was performedas required by 21 CFR111.2600)(1);
e. The initials of the person responsible for the weighing of each component, verifying the weight, and adding each component as required by 21 CFR 111.260(j)(2); and
f. Documentation that quality control personnel reviewed, approved and released each batch for distribution as required by 21 CFR111.260(1)(3).

We acknowledge that in your response, dated September 30, 2014, you stated that you will keep track of all information involving manufacturing. We cannot evaluate the adequacy of your

response because you failed to provide supporting documentation or examples to address these violations.

3. You failed to make and keep the following documentation for equipment and utensils, as required by 21 CFR 111.35:

a. Calibration documentation for instruments you use in manufacturing components in your dietary supplement, as required by 21 CFR 111.35(b)(3). Among other requirements, your documentation must identify the instrument or control calibrated; provide the date of calibration; identify the reference standard used; identify the calibration method used, including appropriate limits for accuracy and precision; and provide the calibration reading or readings found [21 CFR 111.35(b)(3)(i)-(v)].

Specifically, you did not have calibration records for scales used to measure and weigh components for your ALKAZONE® Alkaline Booster with Antioxidant product. Furthermore, you indicated to our investigator that you do not calibrate your scales at all. You must routinely calibrate, inspect, or check your equipment to ensure proper performance, as required by 21 CFR 111.30(c).

b. Documentation of the date of use, maintenance, cleaning, and sanitizing of equipment in individual equipment logs, unless such documentation is kept with the batch record, as required by 21 CFR 111.35(b)(2).

- Specifically,you failed to keep records documenting the cleaning or sanitizing of equipment and utensils used tomanufacture your ALKAZONE® Alkaline Booster with Antioxidant product.
- You also failed to keep records documenting the maintenance performed on equipment used to manufacture your ALKAZONE® Alkaline Booster with Antioxidant product. For example, water is a main ingredient used in your finished dietary supplement; however, you failed to document when you change the filters on your **(b)(4)** system.

We acknowledge that in your response, dated September 30, 2014, you stated that you will keep all documents related to maintenance, cleaning, and sanitation of your equipment. We cannot evaluate the adequacy of your response because you failed to provide supporting documentation or examples to address these violations.

4. You failed to keep records documenting the training your personnel receive including the date of the training, the type of training, and the person(s) trained, as required by 21 CFR 111.14(b). Specifically, your firm failed to keep records documenting how you train your full time

or temporary personnel on how to manufacture, package, label, hold, or distribute your ALKAZONE® Alkaline Booster with Antioxidant product.

We acknowledge that in your response, dated September 30, 2014, you stated that you will train your employees how to properly handle your products. Your response is inadequate because it does not address how you will document this training.

5. You failed to establish written procedures for the review and investigation of product complaints, as required by 21 CFR 111.553. Specifically, you told investigators that you do not have an SOP for the review and investigation of product complaints.

We acknowledge that in your response, dated September 30, 2014, you stated that you will "keep all kinds of information relating to consumer complaints." We cannot evaluate the adequacy of your response because you failed to provide supporting documentation or examples to address this violation.

Misbranded Dietary Supplement:

Even if your ALKAZONE® Alkaline Booster with Antioxidant product was not an unapproved new drug, it would still be a misbranded dietary supplement under section 403 of the Act [21 U.S.C. § 343] because it does not comply with the labeling requirements for dietary supplements.

1. Your ALKAZONE® Alkaline Booster with Antioxidant product is misbranded within the meaning of 403(q)(5)(F) of the Act because the nutrition labeling fails to meet the requirements of 21 CFR 101.36.

Specifically, calories, total fat, sodium, total carbohydrate, and protein are declared as zero on your label; but when such ingredients are present in amounts that can be declared as zero, they must notbe listed on the "Supplement Facts" panel at all, as required by 21 CFR 101.36(b)(2)(i). Additionally, because you have made a claim about
the selenium present in your product, you must declare selenium in a manner in accordance with 21 CFR 101.36(b)(2)(i).

2. Your ALKAZONE® Alkaline Booster with Antioxidant product is misbranded within the meaning of 403(y) of the Act in that the label fails to bear a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with such dietary supplement.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility or 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. 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.

In addition, we have the following comment:

- The net weight of your ALKAZONE® Alkaline Booster with Antioxidant product is declared in U.S. Customary terms only. The net quantity of content should also be declared in terms of metric units in accordance with 15 U.S.C.§1453(a)(2) of the Fair Packaging and Labeling Act (FPLA).

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 working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations cited above. 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 action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

Your response should be addressed to U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey, 07054, Attn: Kerry Kurdilla, Compliance Officer.

Sincerely,
/S/
Diana Amador-Toro
Director

New Jersey District