Inspections, Compliance, Enforcement, and Criminal Investigations

C P Health Products Inc. 7/15/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New York District
Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

July 15, 2014

WARNING LETTER NYK-2014-45

C P Health Products, Inc.
ATTN: Ms. Helen Yang, President
400 Oser Avenue, Suite 2200
Hauppauge, NY 11788

Dear Ms. Yang:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your dietary supplement facility, located at 400 Oser Avenue, Suite 2200, Hauppauge, New York, from October 1 through October 10, 2013 During the inspection you informed the investigator that your firm is a manufacturer and re-packer of dietary supplements and that your firm also does business as Green Pharm. The inspection revealed serious violations of the Current Good Manufacturing Practice (CGMP) regulation for Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Title 21, Code of Federal Regulations (CFR), Part 111 (21 CFR Part 111). These violations cause your dietary supplement products to be adulterated within the meaning of section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(g)(1)], in that the dietary supplement products have been prepared, packed, or held under conditions that do not meet CGMP requirements for dietary supplements.

Additionally, in May 2014 FDA reviewed your product labels and website at the Internet address www.greenpharmaus.com, from which website you take orders for your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare products. The labels and websites promote your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare products for conditions that 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 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 furthe below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

You may find the Act and the CFR through links on FDA's home page at www.fda.gov[1].

Unapproved New Drug Violations:

Examples of some of the claims that provide evidence that your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare products are drugs include:

BellyKetone

- On the label-"Capsaicin has been studied for its effects on pain relief …"

LifeBoost:

- On the label-"It may vitalize entire body so as to decrease the chance of infection."
- "Suggested Use For cancer patients, take 3 capsules three times daily as a nutritional supplement. For a preventive use, take 2-4 capsules a day."

Diabetes Control

- On the label-"Helps Improve Blood Sugar Levels"
- The product name, "Diabetes Control," is a disease claim.
- "Diabetes Control™ is formulated to naturally control the symptoms of diabetes for a more manageable and productive life."
- "Control Diabetes Symptoms"

BreastCare

- "Breast Care™ … is especially blended to help promote breast health by … dispersing swelling."
- "This unique natural remedy is exclusively formulated with therapeutic herbs and nutrient ingredients … such as curcumin for anti-inflammatory and lycopene for cancer prevention…"

Blood Sugar Control

- On the label-"Blood Sugar Control™ … is especially blended to help prevent blood sugar imbalance."
- On the label-"Helps to Stabilize Blood Sugar Levels & Prevent Diabetes Onset"
- "… mulberry leaf containing optimizing levels of 1-deoxynojirimycine (DNJ), appears to … help suppress abnormally high blood glucose levels. The combination of these two precious natural plants may biologically reduce blood pressure, blood glucose … and possibly help prevent diabetes onset."

NeuroCare

- "NeuroCare™ … for Alzheimer's and Parkinson's, is clinically proven to help enormously with its debilitating symptoms, such as speech issues, walking, and the performance of basic daily tasks."
- ". . . a homeopathic formulation for Alzheimer's and Parkinson's, is clinically proven to help enormously with its debilitating symptoms, . . ."

Your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare[1] product are not generally recognized as safe and effective for the above-referenced uses and, therefore, these 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 LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare 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 car use these drugs safely for their intended purposes. Thus, your LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare products 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)].

Dietary Supplement CGMP Violations:

Even if your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control and NeuroCare products did not contain disease claims in their labeling that cause the products to be unapproved new drugs under section 505(a) of the Act [21 U.S.C. § 355(a)], they would still be adulterated dietary supplements within the meaning of section 402(g)(1) of the Act because they have been prepared, packed or held under conditions which do not meet CGMP requirements for dietary supplements. The inspection revealed the following significant violations:

1. Your firm failed to establish product specifications for each dietary supplement that you manufacture for the identity, purity, strength and composition of the finished batch of the dietary supplement, and for limits on those type of contamination that may adulterate or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement, in accordance with 21 CFR 111.70(e). Specifically, your firm has not established product specifications for identity, purity, strength, and composition of any finished dietary supplements manufactured and distributed by your firm.

We received your response dated October 25, 2013, and found it to be inadequate. The information you provided relating to Belly Ketone (Lot # **(b)(4)**), Life Boost (Lot# **(b)(4)**), and Diabetes Control (Lot# **(b)(4)**) fail to provide evidence that you have established such product specifications. Specifically, you provided certificates of analysis (COAs) for Belly Ketone (Lot # **(b)(4)**), LifeBoost (Lot # **(b)(4)**), and Diabetes Control (Lot # **(b)(4)**) products, but these documents do not show that you established product specifications in accordance with 21 CFR 111.70(e). COAs are not acceptable in lieu of a specifications.

Further, you use the HPLC method to assay Raspberry Ketone (Item# **(b)(4)**, Lot# **(b)(4)**), an ingredient in your Belly Ketone (Lot #**(b)(4)**) product. However, you did not provide an identity test for Raspberry Ketone. Nor did you establish specifications to determine the identity of or assay the other ingredients in BellyKetone. In addition, you use the Raspberry Ketone assay result of 49.56 mg/capsule for the Belly Ketone (Lot # **(b)(4)**) labeling claims. However, you did not provide the method you used for the "input" entries for the label claim.

Additionally, you provided microbiological analyses of some types of contaminants that may adulterate your Diabetes Control, Life Boost, and Belly Ketone finished products. This microbiological analyses addressed the contaminants Aerobics Count, Yeast & Mold Count, Staphylococcus aureus, Escherichia coli, and Salmonella sp. However, your firm failed to provide how you established the limits on these contaminants, in accordance with 21 CFR 111.70(e).

2. Your firm failed to meet the requirements of 21 CFR 111.75(a)(1). Before you use a component, you must conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient in your dietary supplement products, in accordance with 21 CFR 111.75(a)(1)(i), unless you petition the agency and the agency exempts you from such testing under 21 CFR 111.75(a)(1)(ii). Specifically, you do not conduct identity testing on any of the components of your dietary supplement that are dietary ingredients. Neither have we received petition from your firm requesting an exemption from such testing, nor have we exempted you from such testing.

We received your response dated October 25, 2013, and found it to be inadequate. Specifically, you provided a certificate of analysis (COA) of the Raspberry Ketone (Lot # **(b)(4)**) and used this ingredient in the manufacture of Belly Ketone product (Lot # **(b)(4)**). However, COAs cannot be used instead of an identity test to verify the identity of dietary ingredients. In addition, this testing must occur prior to using the component, in accordance with 21 CFR 111.75(a)(1)(i) and 21 CFR 111.75(a)(1)(ii). The COAs you provided were dated after the time of inspection and after the manufacturing date.

3. Your firm failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch, in accordance with 21 CFR 111.205(a). Specifically, you did not prepare and follow a written MMR for your Belly Ketone (Lot # **(b)(4)**), LifeBoost (Lot # **(b)(4)**), and Diabetes Control (Lot # **(b)(4)**) products.

We received your response dated October 25, 2013, and found it to be inadequate. You state in your response, "**(b)(4)**," and you attached three exhibits as evidence. However, the documents you provided

are not MMRs but instead appear to be batch production records (BPRs) for your Belly Ketone, LifeBoost, and Diabetes Control products. An MMR must be written and followed for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure the uniformity in the finished batch, from batch to batch.

4. Your firm failed to establish and follow written procedures for the responsibilities of the quality control (QC) operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, in accordance with 21 CFR 111.103. Under 21 CFR 111.123, quality control operations are required to include, for the MMR, BPR, and manufacturing operations, responsibilities such as:

- Determining whether product specifications are met;
- Conducting a material review and making a disposition decision;
- Approving or rejecting any reprocessing;
- Reviewing MMR and BPR documentation;
- Approving and releasing, or rejecting finished dietary supplements.

You failed to establish written procedures for these quality control responsibilities.

Once you have established such written procedures, your quality control personnel must ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the MMR, in accordance with 21 CFR 111.105, and you must make and keep records of such procedures, in accordance with 21 CFR 111.140(b)(1).

We received your response dated October 25, 2013, and found it to be inadequate. Although you provided a Standard Operating Procedure (SOP) for the "Quality Control (QC) Laboratory" procedures, you did not provide documentation of all the established responsibilities for QC operations, nor did you show that these responsibilities were being implemented.

5. Your firm failed to include in your BPR information relating to the production and control of each batch, as required by 21 CFR 111.255(b). Specifically, the BPRs for your Belly Ketone (lot no. **(b)(4)**), Lif Boost (lot no. **(b)(4)**), and Diabetes Control (lot no. **(b)(4)**) did not include the following information relating to the production and control of each batch, as required by 21 CFR 111.260:

- The identity of the equipment and processing lines used in producing the batch [21 CFR 111.260(b)];
- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained [21 CFR 111.260(c)];
- The unique identifier that you assigned to each component, packaging, and label used [21 CFR 111.260(d)];
- A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing [21 CFR 111.260(f)];
- Documentation, at the time of performance, of the manufacture of the batch, including the initials of the person responsible for weighing or measuring each component used in the batch, the initials of the person responsible for verifying the weight or measure of each component used in the batch, the initials of the person responsible for adding the component to the batch, and the initials of the person responsible for verifying the addition of components to the batch [21 CFR 111.260(j)(2)];
- Documentation, at the time of performance, of packaging and labeling operations, including the unique identifier that you assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels; an actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the MMR; and the results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results [21 CFR 111.260(k)];

- Documentation at the time of performance that quality control personnel reviewed the BPR; approved or rejected any reprocessing or repackaging; approved and released, or rejected, the batch for distribution, including any reprocessed batch; and approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement [21 CFR 111.260(l)].

We received your response dated October 25, 2013, and found it to be inadequate. You did not provide documentation showing that you have included all the information required in the batch production records for Belly Ketone (Lot # **(b)(4)**), Life Boost (Lot # **(b)(4)**), and Diabetes Control (Lot # **(b)(4)**) products, in accordance with 21 CFR 111.255 and 21 CFR 111.260.

6. Your firm failed to establish and follow adequate written procedures, for the review and investigation of product complaints, as required by 21 CFR 111.553. Specifically, your established written complaint procedures do not address how your firm will review and investigate product complaints. Any procedures you establish must satisfy the requirements of 21 CFR 111.560 and must be maintained in accordance with 21 CFR 111.570.

We reviewed your response dated October 25, 2013, and found it to be inadequate. Specifically, in your written response, the procedures relating to product complaints entitled "Returned Goods" do not fulfill all of the requirements of 21 CFR 111.560 and 21 CFR 111.570. Furthermore, you provide a document that appears to be a complaint log, rather than written procedures, and the document is not written in English. English translations must be provided for all documents submitted to FDA in a foreign language.

Misbranded Dietary Supplements:

1. Your BellyKetone, LifeBoost, Diabetes Control, BreastCare, Blood Sugar Control, and NeuroCare products are misbranded within the meaning of section 403(s)(2)(B) of the Act [21 U.S.C. § 343(s)(2)(B)] in that the product labels fail to identify the product using the term "dietary supplement" in accordance with 21 CFR 101.3(d) and 21 CFR 101.3(g), which requires that a dietary supplement be identified by the term "dietary supplement" as part of the product's statement of identity, except that the word "dietary" may be deleted and replaced by the name of the dietary ingredients in the product.

2. Your Blood Sugar Control product is misbranded within the meaning of section 403(e)(1) of the Act [21 U.S.C. § 343(e)(1)] because the label fails to specify the place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5.

3. Your BellyKetone, LifeBoost, Diabetes Control, and NeuroCare product labels are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] in that the that the labels fail to identify the part of the plant from which some of the botanical dietary ingredients are derived in accordance with 21 CFR 101.4(h)(1). For example, your LifeBoost fails to identify the part of the plant from which "Schizophyllum Commune", "Cordyceps Sinensis", "Poria Cocos", "Lentinula Edodes", "Agaricus Blazei", "Tremella Fuciformis", "Grifola Frondosa", "Coriolus Versicolor", "Panax Ginseng" and "Hericium Erinaceus" were derived.

4. Your BreastCare product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that the label fails to declare all ingredients by their common or usual name. Your BreastCare product label declares "Vitamin B Complex" but fails to declare the names, quantitative amounts by weight, and percent of the Daily Value of each (b)(2)-dietary ingredient (e.g., each B Vitamin contained in the Vitamin B Complex in accordance with 21 CFR 101.36(b)(2)(i).

5. Your Blood Sugar Control product is misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. § 343(q)(5)(F)] in that the label includes an ingredient list inside the enclosed box of the "Supplement Facts" panel. The ingredient list on dietary supplement products shall be located immediately below the nutrition label or immediately contiguous and to the right of the nutrition label in accordance with 21 CFR 101.4(g).

The violations cited in this letter are not intended to be an all-inclusive list 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 the Act and applicable 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/or injunction.

Within fifteen working days of receipt of this letter, please notify this office 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 action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

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 ir this letter identified non-compliance materially related to a food safety requirement of the Act. Accordingly, FDA may assess fees to cover any reinspection-related costs.

Please send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Kristen C. Jackson. If you have questions regarding any issues in this letter, please contact Kristen Jackson at 718-662-5711.

Sincerely,
/S/
Ronald Pace
District Director
New York District

[1] We recognize that the labeling for NeuroCare identifies the product as homeopathic. The definition of "drug" in section 201(g)(1) of the Act (21 U.S.C. § 321(g)(1)) includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the Act exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval. We acknowledge that many homeopathic drugs are manufactured and distributed without FDA approval under enforcement policies set out in the Agency's Compliance Policy Guide titled, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). As its title suggests, the CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed; thus, in order to fall under the enforcement policies set forth in the CPG, a homeopathic product must meet the conditions set forth in the CPG. The CPG defines a homeopathic drug as: "Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements." The CPG additionally states that "Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products." Although Maidenhair Tree, Rosemary, Sage, Cinnamon, and Nutmeg are all recognized homeopathic ingredients included in the HPUS, Apple Pectin, Natural L-DOPA 40%, Coconut Concentrate, and Trans-Resveratrol are not included in the HPUS or any of its addenda or supplements. Furthermore, to our knowledge, Apple Pectin, Natural L-DOPA 40%, Coconut Concentrate, and Trans-Resveratrol are not listed in any recognized materia medica containing information on the preparation of homeopathic medicines. Therefore, Apple Pectin, Natural L-DOPA 40%, Coconut Concentrate, and Trans-Resveratrol are not homeopathic ingredients and NeuroCare is not considered a homeopathic drug product under the CPG. Accordingly, the policies set forth in the CPG for the marketing of homeopathic drug products do not apply to NeuroCare.

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