C K Solutions, Inc. 8/10/17

U.S. FOOD & DRUG ADMINISTRATION

Denver District Office
P.O. Box 25087
Denver, CO 80225

August 10, 2017

WARNING LETTER

Via UPS Overnight

Ref: # HAF4W(DEN)-17-13-WL

Curtis W. and Karen J. Haderlie, Co-Owners
C K Solutions, Inc. (dba Wind River Herbs)
981 N Main St
Thayne, WY 83127

Dear Mr. and Mrs. Haderlie:

On May 18 and 19, 2017, the U.S. Food and Drug Administration (FDA) conducted an inspection of your dietary supplement manufacturing facility located at 981 N Main St, Thayne, Wyoming. Based on the inspection, a review of the product labels collected during the inspection, and a review of your website, www.windriverherbs.com and associated community website www.localharvest.com, we have identified 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 website at **www.fda.gov (http://www.fda.gov/)**.

To date, we have not received a written response from you.

Unapproved New Drugs

FDA reviewed your website at the internet address www.windriverherbs.com in June 2017 and have determined that you take orders from your website for dietary supplement product s manufactured by your firm. We have also reviewed the national community website www.localharvest.org that you use to promote and sell your dietary supplement products. The dietary supplements on these websites include one or more of the following dietary supplements: Black Cohosh, Echinacea Goldenseal Blend, Milk Thistle Blend, Mullein Blend, Pros Men Blend, Traveler's Aid Blend, Women's Balancing Blend, Baptisia, California Poppy, Elderflower, Elecampane, Ginkgo, Helonias, Horsetail, Lomatium, Pipsissewa, Reishi Mushroom Rhubarb, Usnea, Wild Yam, Yarrow, Black Cohosh Tincture, Osha Lungwort Blend Tincture, Cornsilk Pipsissewa Blend, Kava Kava Tincture, and Clotsfoot Tincture dietary supplements. We have determined that the claims on your website and www.localharvest.org establish that your dietary supplement products are drugs within the meaning of section 201(g)(1)(B) of the Act [21 USC § 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.

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

WWW.WINDRIVERHERBS.COM

Herbal Formula Blends

- Burdock Blend
    - For any infection of the lymph; i.e. swollen nodes, tonsillitis, excessive mucous conditions.*
- Echinacea Goldenseal Blend
    - "Use frequently at the onset of any infection in the body (colds, flu, viral problems, staph infections, congested lymph)."
- Ginkgola Blend
    - "Also good for tinnitus.*"
- Lomatium Astragalus Blend
    - "Used daily as a preventative tonic for viral infections.*"
- Milk Thistle Blend:
    - "For liver congestion and toxicity. Helpful in constipation due to bile insufficiency; hemorrhoids…"
- Mouth Tonic
    - "The herbs in this blend are anti-inflammatory, antiseptic…"
- Mullein Blend:
    - "For outer ear infections in adults and children..."
- Osha Lungwort Blend
    - "For acute or chronic upper respiratory infections.*
- Pros Men Blend
    - "For acute or chronic prostatitis."

- Red Root Throat Blend
    - “Relieves pain and discomfort of sore throat, swollen lymph nodes and tonsillitis.*”
- Skullcap Valerian Blend
    - “A sedative formula for restlessness and sleep disturbances…chronic tension and insomnia.*”
- Traveler’s Aid Blend
    - “For dysentery while traveling in Third World countries... In acute situations take a dropperful every hour. For best results take 10 days before planned travel.”

Single Herb Extract

- Baptisia
    - “For inflammation such as larylngitis [sic], tonsillitis, or pharyngitis…”
- Barberry root
    - “Useful for intestinal parasites, especially giardia.*
- Basil aerial parts
    - Treats fevers, cold and flu. Alleviates stomach cramps, vomiting and indigestion.*
- Black Haw root
    - “[M]ay also help reduce blood pressure.*
- Balck Walnut hulls
    - “Anitseptic and anti-fungal.*”
- Bladderwrack plant
    - “Treatment for underactive thyroid and goiter. Relieves joint inflammatioin from rheumatoid arthritis.*”
- Blue Cohosh root
    - “Antispasmodic for colic, asthma or cough…*”
- Bogbean leaf
    - “Most useful in treating rheumatoid arthritis”
- Celery Seed Diuretic
    - “Treats arthritis, gout and rheumatoid arthritis.*”
- Chamomile, German flowers
    - “Useful for…insominia.”
- Coltsfoot aerial parts
    - “Expectorant used in chronic respiratory conditions, bronchitis and emphysema.*”
- Cornsilk

- “Used in urinary tract infections...*”

- Elderflower
  - “Fever reducer in adults and children.”
- Elecampane root
  - “Specific for bronchial coughs, especially in children. Expectorant for emphysema and asthma.”
- Eyebright aerial parts
  - “Relieves acute & chronic eye inflammations. Also for conjunctivitis, nasal congestion and sinusitis.*”
- Ginkgo leaves
  - “Helpful in memory loss, tinnitus…eye problems. Useful in Alzheimer’s disease.”
- Helonias root:
  - “Used for…threatened miscarriage…”
- Horsetail
  - “Diuretic for treatment of incontinence & bed wetting. Used for inflammation of prostate gland.”
- Juniper Berry
  - “Antiseptic/diuretic used for treatment of cystitis. Used for joint/muscle pain.”
- Lemon Verbena leaf
  - “Relieves nervous disorders…”
- Linden Flower aerial
  - “Good for arteriosclerosis & hypertension, treatment of high blood pressure.*”
- Lomatium root
  - “Antiviral herb for Epstein Barr virus, Herpes Simplex I & II, Candida Albicans & AIDS. Used for colds, flu & respiratory infections.”
- Pau D'Arco bark
  - “Inhibits Candida growth…has been shown to inhibit growth of tumors.*”
- Pipsissewa aerial
  - “For urinary tract infections and kidney inflammations…”
- Pleurisy Root
  - “Treatment of bronchitis & respiratory infections. Antispasmodic useful for pleurisy and pneumonia.*”
- Reishi Mushroom
  - “…A deterrent for high blood pressure & heart disease. Also lowers cholesterol.”
- Rhubarb root

- “Good for constipation, worms, dysentery, diarrhea…”

- Saw Palmetto berry
  - “Used for enlared prostate.*”

- Usnea lichen
  - “Antibiotic with a similar action as penicillin. Excellent for pneumonia, bronchitis, cold & flu. Also colitis & vaginal infections.”

- Wild Yam root
  - “For…ovarian and uterine pain & nausea. For rheumatoid arthritis. Relieves spasms of intestines & diverticulitis.”

- Yarrow aerial
  - “Promotes sweating in fevers. Dilates blood vessels, lowering blood pressure…Aids in cystitis.”

WWW.LOCALHARVEST.ORG

- Osha Lungwort Blend Tincture
  - “Upper respiratory support: bronchitis, pleurisy, asthma, or any congested lung problem.”
  - “USAGE: A formula for bronchitis, pleurisy, asthma, or any congested lung problem…antiseptic to the pleura of the lungs, reducing infection…Also helpful in asthma to keep the lungs clear and bronchials dilated.”

- Black Cohosh Tincture – Cimicifuga racemose:
  - “Clinical results show improvement in…headache…tinnitus…depression.”
  - This herb is useful in treating inflammatory arthritis and rheumatism. The sedative action in Black Cohosh is helpful in treating high blood pressure, whopping cough, and asthma.”

- Cornsilk Pipsissewa Blend
  - “A blend of… anti-inflammatory…antiseptic herbs.”
  - “USAGE: For burning, painful urinary tract infections…herbs in formula are diuretic…to carry out harmful bacteria…also antiseptic…will reduce heat and burning in urinary tract infections.”

- Kava Kava Tincture – Piper methysticum
  - “Antispasmodic… antifungal, analgesic, muscle relaxant, anticonvulsant.”

- Coltsfoot Tincture – Tussilago farfara
  - “Expectorant used in chronic respiratory conditions, bronchitis and emphysema.”

- Linden Flower Tincture – Tilia platyphyllos
  - “Good for arteriosclerosis & hypertension. Treatment of high blood pressure.”

- Burdock Blend Tincture
  - “For chronic skin eruptions.”
  - “This blend is drying for congestion, phlegm and moisture that leads to chronic infection and some deeper diseases. It also purifies the lymphatic system and blood relative to infection and accentuates immune response. It is formulated with herbs that are traditionally considered to be anti-cancer remedies.”

- Celery Seed Tincture – Apium graveolens
    - o “Treats arthritis, gout and rheumatoid arthritis.”

Your 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)(1) of the Act [21 USC § 321(p)(1)]. New drugs may not be legally marketed in the United States without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 USC §§ 331(d) and 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Burdock Blend, Echinacea Goldenseal Blend, Mullein Blend, Osha Lungwort Blend, Pros Men Blend, Red Root Throat Blend, Skullcap Valerian Blend, Baptisia, Blue Cohosh root, Coltsfoot aerial parts, Elecampane root, Ginkgo leaves, Juniper Berry, Linden Flower aerial, Lomatium root, Pleurisy Root, Usnea lichen, Wild Yam root, Yarrow aerial products are intended for treatment of one or more diseases that are not amendable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, these products fail to bear adequate directions for their intended use and, therefore, these products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of these misbranded drugs violates 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, these products, along with all your dietary supplements, 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 manufactured under conditions that do not meet the Current Good Manufacturing Practice (CGMP) regulations for Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, *Title 21, Code of Federal Regulations,* Part 111 (21 CFR Part 111).

During the inspection, you indicated that you have not complied with CGMP requirements for dietary supplements. Our FDA investigator observed the following significant violations of these CGMP requirements:

1. 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, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Specifically, during the inspection our investigator observed that that you did not have any written procedures for quality control operations for the manufacture of your dietary supplement products.

You must implement quality control operations into your manufacturing, packaging, labeling, and holding operations for producing dietary supplements, as required by 21 CFR 111.65.

2. You failed to establish specifications for any points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 CFR 111.70(a).

Specifically, you failed to establish the following component specifications for each component that you use in the manufacture of a dietary supplement:

- Identity specification [21 CFR 111.70(b)(1)];
- 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
- Specifications that establish the limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement [21 CFR 111.70(b)(3)];

Further, you failed to establish 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 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 111.70(e).

You must determine whether the specifications that you establish under 21 CFR 111.70 are met, as required by 21 CFR 111.73. Specifically, you must conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, as required by 21 CFR 111.75(a)(1)(i), unless you petition the agency under 21 CFR 111.75(a)(1)(ii) and the agency exempts you from such testing. You must also confirm the identity of other components and determine whether other applicable component specifications established in accordance with 21 CFR 111.70(b) are met, as required by 21 CFR 111.75(a)(2). Further, to determine you meet product specifications for the finished dietary supplement batches, you must conduct testing, as required by 21 CFR 111.75(e).

You must make and keep records, including records of the specifications you establish, in accordance with 21 CFR 111.95.

3. You failed to prepare and follow a written master manufacturing record 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 as required by 21 CFR 111.205(a).

Specifically, during the inspection, you were not able to provide MMRs for your Black Cohosh, Echinacea Goldenseal Blend, Milk Thistle Blend, and Siberian Ginseng dietary supplement products. Furthermore, you indicated that you did not have MMRs for any of the dietary supplements you manufacture.

4. Your batch production records (BPRs) failed to include complete information relating to the production and control of each batch, as required by 21 CFR 111.255(b) and 21 CFR 111.260.

Specifically, your BPR’s for Black Cohosh (Batch # 111272016), Echinacea Goldenseal Blend (Batch #FM30032217), Milk Thistle Blend (Batch # FM10040517), and Siberian Ginseng (Batch #438312016) fail to include the following:

- 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)];
- A statement of the actual yield and the percentage of theoretical yield at appropriate phases of processing [21 CFR 111.260(f)];

- Documentation that the finished dietary supplement meets specifications established in accordance with 21 CFR 111.70(e) and (g) [21 CFR 111.260(i)];
- Documentation, at the time of performance, of the initials of the persons performing each step, including:
    - o The initials of the person responsible for weighing or measuring of each component [21 CFR 111.260(j)(2)(i);
    - o The initials of the person responsible for verifying the weight or measure of each component used in the batch [21 CFR 111.260(j)(2)(ii);
- Documentation, at the time of performance, of packaging and labeling operations including, an actual or representative label, or cross-reference to the physical location of the actual or representative label specified in the master manufacturing record [21 CFR 111.260(k)(2)];
- Documentation, at the time of performance that quality control personnel:
    - o Reviewed the batch production record [21 CFR 111.260(l)(1)];
    - o Approved and released, or rejected, the batch for distribution [21 CFR 111.260(l)(3)];
    - o Approved and released, or rejected, the packaged and labeled dietary supplement [21 CFR 111.260(l)(4).

5. You failed to establish and follow written procedures to fulfill the requirements related to packaging and labeling operations, as required by 21 CFR 111.403. Specifically, you have not established written procedures for packaging and labeling operations.

6. You failed to establish and follow written procedures to fulfill the requirements related to product complaints, as required by 21 CFR 111.553. Specifically, you have not established written procedures for handling product complaints. In addition, you must ensure product complaints are reviewed and investigated as required by 21 CFR 111.560 and written records of product complaints that are related to good manufacturing practice and subsequent investigations are maintained as required by 21 CFR 111.570(b)(2).

7. You failed to establish and follow written procedures to fulfill the requirements related to returned dietary supplement, as required by 21 CFR 111.503. Specifically, our investigator found your firm does not have written procedures regarding the handling of returned dietary supplements. Additionally, you failed to make and keep records of a material review and disposition decision on a returned dietary supplement, as required by 21 CFR 111.535(b)(2).

8. You failed to establish and follow written procedures for holding and distribution operations, as required by 21 CFR 111.453. Specifically, you have not established written procedures for holding and distributing operations.

9. You failed to establish and follow written procedures for cleaning the physical plant and for pest control, as required by 21 CFR 111.16. Specifically, you have not established written procedures for cleaning the physical plant and for pest control.

10. You failed to establish and follow written procedures for fulfilling the requirement for equipment and utensils, including written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements, as required by 21 CFR 111.25(c). Specifically, you have not established these written procedures.

Misbranded Dietary Supplements

Your Siberian Ginseng, Milk Thistle Blend, Echinacea Goldenseal Blend, and Black Cohosh products (hence forth known as “Your products”) are misbranded dietary supplements under section 403 of the Act [21 U.S.C. § 343]

because they do not comply with the labeling requirements for dietary supplements as required by 21 CFR 101.

1. Your Siberian Ginseng product is misbranded within the meaning of section 403(u) of the Act [21 U.S.C. § 343(u)], in that it purports to contain ginseng, but the purported ginseng ingredient is not from a plant classified with the genus Panax. Section 403(u) of the Act, added by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), provides that the term “ginseng” may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plan classified within the genus Panax. Specifically, your product contains an ingredient identified as Siberian Ginseng. That ingredient may not be declared under a name that includes the term “ginseng” because it is not from the genus Panax.

2. Your Siberian Ginseng, Milk Thistle Blend, Echinacea Goldenseal Blend, and Black Cohosh products are misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343(q)(1)(A)] in that the labels fail to declare a serving size as required by 21 CFR 101.36(b)(1)(i). The terms “serving” or “serving size” for a dietary supplement are defined in 21 CFR 101.9(b) and 101.12, Table 2, as the maximum amount recommended on the label for consumption per eating occasion. The serving size must include a common household measure followed by the equivalent metric quantity in parentheses in accordance with 21 CFR 101.9(b)(7).

3. Your Echinacea Goldenseal Blend and Milk Thistle Blend are misbranded within the meaning of section 403(s)(2)(C) of the Act [U.S.C. § 343(s)(2)(C)] in that the labels fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 CFR 101.4(h)(1) and 101.36(d)(1). Specifically:

- Your Echinacea Goldenseal Blend label fails to include the part of the plant from which Echinacea (angustifolia), Echinacea (purpurea) and Goldenseal are derived.
- Your Milk Thistle Blend label fails to include the part of the plant from which the Milk Thistle, Burdock, Toadflax, and Blue Vervain are derived.

4. Your Siberian Ginseng, Milk Thistle Blend, Echinacea Goldenseal Blend, and Black Cohosh products are misbranded within the meaning of Section 403(e)(1) of the Act [21 U.S.C. § 343 (e)(1)] in that the labels fails to list the place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5(d). Specifically, the product labels fail to include the zip code.

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility or in connection with your products or their labeling. 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 all of the products you manufacture or distribute meet all of the requirements of the Act and FDA regulations. You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

We offer you the following labeling comments:

- The title “Supplement Facts’ on the labels of your Siberian Ginseng, Milk Thistle Blend, Echinacea Goldenseal Blend, and Black Cohosh products is not set full width of the nutrition label and bolded to distinguish it from other information as required by 21 CFR 101.36(e)(1).
- Your Echinacea Goldenseal Blend and Milk Thistle Blend product labels fail to declare the dietary ingredients in the blends in a column or linear display indented under the blend name in accordance with 21 CFR 101.36(c)(2).
- Your Echinacea Goldenseal Blend and Milk Thistle Blend product labels fail to include a heavy bar after the last dietary ingredient in accordance with 21 CFR 101.36(e)(6)(ii).