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

Pick and Pay Inc dba Cili Minerals 5/8/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
FAX: (615) 366-7802

May 8, 2015

WARNING LETTER NO. 2015-NOL-09

UNITED PARCEL SERVICE
Delivery Signature Requested

Anton S. Botha, Owner/CEO
Pick and Pay, Inc., dba Cili Minerals
600 Guilbeau Road, Suite C
Lafayette, Louisiana 70506-8405

Dear Mr. Botha:

On November 6, 10, 12-14, and 19, 2014, investigators with the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility, located at 113 Pine Park Drive, Lafayette, Louisiana. Enclosed for your reference is the form FDA 483 containing the investigator's observations, which was also issued to your representative at the close of the inspection. Based on our inspection and subsequent review of your product labeling collected during the inspection, as well as your firm's website, 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 Internet home page at **www.fda.gov (http://www.fda.gov/)**.

Unapproved New Drugs

FDA reviewed your website at the Internet address www.cilihealthstore.com in February 2015 and determined you take orders at this website for the products "PoLith," "Lithium," "Germanium," "CilZinCo," "Cilver," and "ADD-Ease," which the website promotes for conditions that cause the products to be drugs under Section 201(g)(1)(B) of the Act [21 *United States Code* (USC) 321(g)(1)(B)]. The therapeutic claims on your website establish these 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 some of the website claims which provide evidence that your products are intended for use as drugs include:

PoLith

- "[I]t might help mental disorders…"
- "[A]dhd, autism, bipolar disorder, brain injury, epilepsy, hepatitis…liver cirrhosis, parkinson's [*sic*] disease…stroke."

Lithium

- "DOCTOR PRESCRIPTION REQUIRED""[A]dhd, anxiety, autism, bipolar disorder, cluster headaches, epilepsy…manic depression, panic attacks, parkinson's [*sic*] disease, stroke."

Germanium

- "[G]ermanium is used for heart and blood vessel conditions, including high blood pressure, high cholesterol, and heart disease; for eye conditions, including glaucoma and cataracts; and for liver conditions, including hepatitis and cirrhosis…."
- "[A]llergies, asthma…high blood pressure, hypertension, leukemia, liver cirrhosis, neuralgia."
- "People use it as medicine. Despite serious safety concerns, germanium is used for heart and blood vessel conditions, including high blood pressure, high cholesterol, and heart disease; for eye conditions, including glaucoma and cataracts; and for liver conditions, including hepatitis and cirrhosis. Some people use germanium for osteoarthritis, rheumatoid arthritis (RA), pain, weak bones (osteoporosis)…and AIDS. Other uses include heavy metal poisoning, including mercury and cadmium poisoning; depression; food allergies; and yeast and viral infections."

CilZinCo

- "[C]olitis…diarrhea, herpes…meningitis, shingles…whooping cough…"

Cilver

- "[A]nti-viral, bird flu, common cold, e coli, flu, influenza, meningitis, shingles…swine flu, whooping cough."

ADD-Ease

- The name of the product "ADD-Ease" is a claim for the mitigation of attention deficit disorder in the context of your website labeling.
- "ADD (Attention Deficit Disorder) can generally be described as a group of symptoms that affect concentration and a person's ability to focus."
- "[A]dd, adhd…Attention Deficit Disorder…bipolar disorder…chronic fatigue… depression, diabetes…"

Your "PoLith," "Lithium," "Germanium," "CilZinCo," "Cilver," and "ADD-Ease" 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 USC 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 USC 355(a)]; see also Section 301(d) of the Act [21 USC 331(d)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate the drug is safe and effective.

Misbranded Drugs

Furthermore, your "PoLith," "Lithium," "Germanium," "CilZinCo," "Cilver," and "ADD-Ease" 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 these drugs safely for their intended purposes. Thus, these drugs are misbranded within the meaning of Section 502(f)(1) of the Act, because their labeling fails to bear adequate directions for use [21 USC 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of Section 301(a) of the Act [21 USC 331(a)].

Adulterated Dietary Supplements

The November 6, 10, 12-14, and 19, 2014 inspection revealed significant violations of the Current Good Manufacturing Practice (CGMP) regulations for dietary supplement. These violations cause the "Magnesium," "Calcium," "Bone Structure," and "Water of Life" products manufactured at your facility to be adulterated within the meaning of Section 402(g)(1) the Act [21 USC 342(g)(1)] because they have been prepared, packed, or held under conditions that do not meet the CGMP regulations for dietary supplements, Title 21*, Code of Federal Regulations*, Part 111 (21 CFR 111).

Specifically, during the inspection, the FDA investigator observed the following significant violations:

1. You failed to establish product specifications for the identity, purity, strength, and composition for each dietary supplement that you manufacture, as required by 21 CFR 111.70(e). Specifically, you have set Total Dissolved Solids (TDS) level for each of your dietary supplement products, however, the TDS level is not an adequate specification for the identity, purity, strength, or composition of your finished liquid mineral dietary supplement product because TDS measures the combined content of all inorganic and organic dissolved solids in a liquid, but cannot identify or distinguish between any of the substances.

Once you have established identity specifications in accordance with 21 CFR 111.70(e) as stated above, you are required to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use, as required by 21 CFR 111.75 (a)(1)(i), which you also failed to do. Specifically, you stated that you do not test or examine incoming ingredients prior to use in finished product.

2. You failed to make and keep documentation of calibrations, each time the calibration is

performed, for instruments or controls that you use in manufacturing or testing a component or dietary supplement, as required by 21 CFR 111.35(b)(3). Specifically, you stated that you do not maintain records for the calibration of your reverse osmosis machine.

3. You failed to make and keep documentation, in individual equipment logs or with the batch record, of the date of maintenance of the equipment, as required by 21 CFR 111.35(b)(2). Specifically, you stated that you do not maintain documentation on the maintenance of the municipal water pre-filter and the reverse osmosis filter used to manufacture dietary supplements.

4. You failed to adequately install and maintain your plumbing to avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition, as required by 21 CFR 111.15(f)(3). Specifically, there is no backflow prevention device on the hose bib that connects to a green plastic hose that supplies water for washing floors of the manufacturing facility. This green hose was observed to be in a floor drain inside the building. Without a backflow prevention device, water from the floor drain can backflow through the hose and contaminate the facility's water supply pipes.

Misbranded Dietary Supplements

The review of your product labels for "Magnesium," "Calcium," "Water of Life," and "Bone Structure" determined that they are misbranded dietary supplements under Section 403 of the Act [21 USC 343] because they do not comply with the labeling requirements for dietary supplements. Specifically:

1. Your "Water of Life" and "Bone Structure" products are misbranded under Section 403(q)(5)(F) of the Act [21 USC 343(q)(5)(F)] because the presentation of the nutrition information on the labeling of your products do not comply with 21 CFR 101.36.

Specifically:

- Your "Water of Life" product fails to present the trace mineral ingredients that are part of the proprietary blend inside the Supplement Facts panel, as required by 21 CFR 101.36(c).
- Your "Bone Structure" product fails to declare each mineral ingredient by their quantitative amount by weight, as required by 21 CFR 101.36(b)(2)(i)(A), but instead declares each amount in parts per million (ppm). In addition, the ingredients that have Reference Daily Intake (RDI) as established in 21 CFR 101.9(c) and not declared in the order required by 21 CFR 101.36(b)(2)(i)(B).

2. Your “Magnesium,” “Calcium,” “Water of Life,” and “Bone Structure” products are misbranded under Section 403(s)(2)(B) of the Act [21 USC 343(s)(2)(B)] because the product labels fail to identify the product by using the term “dietary supplement” in accordance with 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 ingredient in the product or an appropriately descriptive term.

3. Your “Magnesium,” “Calcium,” “Water of Life,” and “Bone Structure” products are misbranded under Section 403(e)(1) of the Act [21 USC 343(e)(1)] because the product labels fail to list the place of business of the manufacturer, packer, or distributor in accordance with 21 CFR 101.5.

The violations cited in this letter are not intended to be an all-inclusive statement of violations which exist at your facility or in connection with your products. You are responsible for investigation and determining the causes of the violations identified above and for preventing their recurrence or occurrence of other violations. It is your responsibility to assure 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/or injunction.

We note that you declare high levels and percent Daily Values for minerals in your products containing selenium, molybdenum, iodine, copper, and chromium that exceed the Upper Tolerable Intake Levels (ULs) set by the Institute of Medicine. Examples of your products with such declarations include, but are not limited to: “Selenium,” “Molybdenum,” “Iodine,” “Hypo Support,” “CilZinCo,” “Chromium,” and “ADD-Ease.” You should verify that your products actually contain the declared amount(s). If your products do contain the amounts listed, you should consider reformulating the products or changing the serving size to remove the potential for toxicity.

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.

Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timeframe for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time in which the corrections will be completed.

Please send your reply to Kari L. Batey, Compliance Officer, Food and Drug Administration, at the above address. Any questions you may have regarding this process should be directed to Ms. Batey at (615) 366-7808.

Sincerely,
/S/
Ruth P. Dixon
District Director
New Orleans District

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

2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

2014 (/ICECI/EnforcementActions/WarningLetters/2014/default.htm)

2013 (/ICECI/EnforcementActions/WarningLetters/2013/default.htm)

2012 (/ICECI/EnforcementActions/WarningLetters/2012/default.htm)

2011 (/ICECI/EnforcementActions/WarningLetters/2011/default.htm)

2010 (/ICECI/EnforcementActions/WarningLetters/2010/default.htm)

2009 (/ICECI/EnforcementActions/WarningLetters/2009/default.htm)

2008 (/ICECI/EnforcementActions/WarningLetters/2008/default.htm)

2007 (/ICECI/EnforcementActions/WarningLetters/2007/default.htm)

2006 (/ICECI/EnforcementActions/WarningLetters/2006/default.htm)

2005 (/ICECI/EnforcementActions/WarningLetters/2005/default.htm)

Tobacco Retailer Warning Letters (/ICECI/EnforcementActions/WarningLetters/Tobacco/default.htm)