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

Morguetorium, LLC 2/4/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration

February 4, 2016

WARNING LETTER

VIA OVERNIGHT DELIVERY
RETURN RECEIPT REQUESTED

Chad Bolinger
MorgueJuice.com
(b)(6)

11530 Ridge Rd.
Suite 5
Thackerville, OK 73459
Kodak.chaos@gmail.com

Dear Chad Bolinger:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your web site at the internet address www.morguejuice.com in January 2016 and has determined that you take orders there for the product "Morgue Juice," which you claim contains cannabidiol (CBD). The claims on your website establish that the product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)], because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at **www.fda.gov (http://www.fda.gov/)**.

Examples of claims observed on your website that establish the intended use of your product include, but may not be limited to, the following:

On the webpage titled “Facts About CBD”:

Under the heading, “FACTS ABOUT CBD”:

- “[A]n appealing treatment option for patients seeking anti-inflammatory, anti-pain, anti-anxiety, anti-psychotic . . . .”

Under the heading, “SCIENCE”:

- “CBD directly activates serotonin receptors, causing an anti-depressant effect . . . .”
- “CBD kills breast cancer . . . .”
- “Cannabidiol . . . could treat aggressive forms of cancer without any of the painful side effects of chemotherapy . . . .”
- “CBD is an effective painkiller – particularly for peripheral neuropathy . . . associated with cancer, multiple sclerosis, diabetes, arthritis, and other neurodegenerative conditions.”

Under the heading, “CONDITIONS”:

- “CBD may be therapeutic for many conditions, including . . . ADD/ADHD . . . Addiction . . . AIDS . . . ALS . . . Alzheimer’s . . . Antibiotic resistance . . . Atherosclerosis . . . Arthritis . . . Asthma . . . Autism . . . Bipolar . . . Cancer . . . Colitis/Crohn’s . . . Depression . . . Diabetes . . . Heart disease . . . Huntington’s . . . Kidney disease . . . Liver disease . . . Multiple Sclerosis . . . Obesity . . . Osteoporosis . . . Parkinson’s . . . Prion/Mad Cow disease . . . PTSD . . . Schizophrenia . . . Sickle cell anemia . . . Spinal cord injury . . . Stroke/TBI”

Your product “Morgue Juice” is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a “new drug” 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 the FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 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 product “Morgue Juice” is intended for treatment of one or more diseases that are not amenable 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 product safely for its intended purposes. Accordingly, “Morgue Juice” fails to bear adequate directions for its intended uses and, therefore, the product is 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 this misbranded drug violates section 301(a) of the Act [21 U.S.C. § 331(a)].

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products and 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 assure 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.

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 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. Your response should be sent to:

U.S. Food and Drug Administration
CDER/OC/OUDLC
10903 New Hampshire Avenue, WO51
Silver Spring, MD 20993-0002
FDAADVISORY@fda.hhs.gov (mailto:FDAADVISORY@fda.hhs.gov)

Sincerely,
/S/
Ilisa Bernstein, Pharm.D., J.D.
Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)