State of New Jersey
DEPARTMENT OF HEALTH
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March 11, 2021

Devra Karlebach, CEO
GTI New Jersey, LLC
196 3rd Ave. #3C
Paterson, NJ 07514

Brian Kiniry, Senior Vice President
Curaleaf NJ, Inc.
640 Creek Road
Bellmawr, NJ 08031

Notice of Violation for cultivation, processing or dispensing medical cannabis products containing fungus

Dear Ms. Karlebach and Mr. Kiniry:

This letter is a joint Notice of Violation in accordance with N.J.A.C. 8:64-13.8 for both Curaleaf NJ II, Inc. ("Curaleaf") and GTI New Jersey ("GTI"). Both Alternative Treatment Centers were found to have cultivated, processed, or dispensed medical cannabis that, upon examination, contained a form of common fungus: penicillium.

N.J.A.C. 8:64-10.7(a) states:

(a) An ATC shall process marijuana in a safe and sanitary manner to protect registered qualifying patients from adulterated marijuana and shall process the dried leaves and flowers of the female marijuana plant only, which shall be:

1. Well cured and free of seeds and stems;

2. Free of dirt, sand, debris or other foreign matter; and

3. Free of mold, rot or other fungus or bacterial diseases.

Both Curaleaf and GTI acted in violation of N.J.A.C. 8:64-10.7(a) by cultivating, processing, and/or dispensing medical cannabis products containing penicillium.

On January 22, 2021, the Department was notified of a complaint from a patient alleging medical cannabis flower purchased at Rise Dispensary (GTI) contained visible mold. The picture submitted by the patient is attached to this letter.

The patient returned the product to Rise Dispensary and the Department arranged to take a sample from the product and submit it to the Department's Public Health Environmental and Agricultural Laboratories ("PHEAL") for examination.

On 2/11, the plant pathologist made the determination that the sample contained Penicillium sp, a common fungus.

The Department then ordered all products associated with the batch in question – batch "Bananas Foster BF.F5.H150, cultivated by Curaleaf and dispensed by GTI – to be quarantined. Additionally, related batches at Curaleaf were ordered to be quarantined (BF.F3.H151 and BF.F1.H152).

To confirm the results, the Department collected additional samples of the batches in question from GTI and Curaleaf. All three samples from GTI contained visible fungal activity after 3 days in a moist chamber and a determination of Penicillium was made for all three samples after 7 days of incubation. Additionally, the samples taken from Curaleaf also showed fungal activity after 3 days of incubation.

The results of those examinations are also attached.

On February 19th, The Department notified both Curaleaf and GTI of the results of the examination and asked both ATCs to initiate a voluntary recall for all affected products. On February 21, both GTI and Curaleaf submitted letters to the Department that were wholly insufficient in adequately notifying patients about the potential presence of a plant pathogen and furthermore were inconsistent with even their internal recall standard operating procedures ("SOPs") for recalls. The letters did not identify mold, did not reference penicillium and offered patient's little detail otherwise.

Therefore, in accordance with N.J.A.C. 8:64-13.8, and due to **1) the confirmed presence of Penicillium sp. in product dispensed to a patient and 2) the accelerated development of Penicillium sp. on products sampled from both Curaleaf and GTI**, the Department hereby orders Curaleaf and GTI to submit and institute corrective action plans for violations of N.J.A.C. 8:64-10.7(a).

Corrective action plans shall include, at a minimum:

- The issuance of recalls to all patients that purchased implicated products, for all implicated products, in accordance with relevant recall SOPs;
- Recall notices shall advise patients with any questions or concerns about mold allergies to contact their healthcare provider;
- Plans for the inspection and periodic monitoring of potential fungal activity in GTI and Curaleaf facilities;
- Updated SOPs for quality control that include routine visual inspections for mold/fungus during cultivation, processing and dispensing; and

- The destruction of any product remaining at GTI and Curaleaf associated with the following batches:
    - Bananas Foster BF.F5.H150
    - Bananas Foster BF.F3.H151
    - Bananas Foster BF.F1.H152

GTI and Curaleaf have 24 hours to submit an updated recall notice to the Department for approval, and 7 days to submit a complete corrective action plan for the aforementioned violations.

Failure to submit a corrective action plan in 7 days shall result in further disciplinary action.

Sincerely,

Jeff Brown
Assistant Commissioner, Medicinal Marijuana