# EXECUTIVE SUMMARY:

## Recall of Beneleaves Limited Eric + Eric Turtle Brownie Bites

February 15, 2022

## I. Introduction

The Ohio Medical Marijuana Control Program (MMCP) is administered by three state agencies: the State of Ohio Board of Pharmacy (Pharmacy Board), the Ohio Department of Commerce (Commerce), and the Ohio State Medical Board (Medical Board). Beneleaves Limited (Beneleaves), located in Columbus, Ohio, is licensed as a stand-alone processor by the Ohio Department of Commerce. On August 12, 2021, the MMCP issued a mandatory recall[1] for product manufactured by Beneleaves. This recall notified the public that the MMCP had received reports of mold on the product. The MMCP placed an administrative hold on and quarantined the product, preventing it from being sold to patients.

## II. Background

The Pharmacy Board is responsible for the licensing and regulation of dispensaries, and the registration of patients and caregivers. Commerce is responsible for the licensing and regulation of cultivators, processors, and testing laboratories. Beneleaves is a processor licensed to manufacture and sell medical marijuana products to dispensaries.

Licensed processors manufacture medical marijuana products and are required to track their inventory in MMCP's seed-to-sale inventory tracking system, Metrc. This system tracks the medical marijuana product as it grows, is manufactured, and tested. A sample of each lot of medical marijuana product is required to be tested before the lot of product is transferred to a dispensary. After the required testing is performed and the product passed the required analysis, the product can then be sold to a dispensary.

The Beneleaves Brownie Bites subject to this recall passed all required testing prior to being delivered to dispensaries. After distribution to dispensaries, some Brownie Bites developed minimal microbial growth, which was later identified through laboratory testing as yeast. Yeast growth is affected by conditions such as temperature, pH, and sugar concentration, and can grow on almost any type of food at any time.[2]

## III. Recall

On August 5, 2021, the MMCP received a report from a dispensary that Beneleaves Eric + Eric Turtle Brownie Bites had, what appeared to be, visible microbial growth on them. This was reported after a patient purchased the Brownie Bites and returned to the dispensary approximately 25 minutes later to report the issue. After further investigation by the MMCP

[1] See Attachment A

[2] U.S. Food and Drug Administration, *Bacteriological Analytical Manual Chapter 18: Yeast, Molds and Mycotoxins*, Valerie Tournas, Michael E. Stack, Philip B. Mislivec, Herbert A. Koch and Ruth Bandler (April 2001) https://www.fda.gov/food/laboratory-methods-food/bam-chapter-18-yeasts-molds-and-mycotoxins

and speaking with Beneleaves representatives, it was determined that the products posed a public health concern and were subject to recall.

The Department of Commerce MMCP, in coordination with the Ohio Board of Pharmacy, on August 12th issued a mandatory recall on the affected products, placed an administrative hold on the products at the processor, and quarantined the products at the dispensary so they could not be sold to patients.

On September 9th, North Coast Testing Laboratory selected samples of the affected product for testing. The lab reported on October 11th that samples collected tested positive for yeast, which had grown on some of the products.

On December 2nd, Department of Commerce MMCP staff met with Beneleaves representatives and instructed them to destroy the products subject to the recall. The MMCP also authorized Beneleaves to resume the manufacture of the Turtle Brownie Bites with corrective actions and quality assurance measures in place.

**The MMCP performed the following actions as a result of the product recall and administrative hold:**

- Identified all products located at the processor and dispensaries that were affected by the recall
- Communicated to patients that recalled products may be returned to dispensaries
- Required Beneleaves to collect all unsold products located at dispensaries
- Required Beneleaves to submit to additional laboratory testing
- Required product returned by patients to be destroyed at the return dispensary location
- Required Beneleaves to destroy any remaining product subject to the recall

**Beneleaves Limited performed the following actions related to the product recall:**

- Cooperated with the MMCP investigation into the matter and responded to all requests from the Department
- Conducted an internal investigation of product issues
- Submitted recalled products for additional laboratory testing
- Conducted testing on packaging
- Conducted environmental testing
- Developed a corrective action plan, including future shelf-life testing and reformulation with additional antimicrobials utilized
- Shortened the shelf-life declaration for the Eric + Eric Turtle Brownie Bites
- Updated its Standard Operating Procedures (SOP)

## IV. Recall Metrics

<u>Products Recalled</u>

- Eric + Eric Turtle Brownie Bites

Product IDs[3] Recalled

- M00000174921: Edb Oral Admin - 16.6 - 0 - 2 - Eric + Eric Turtle Brownie Bites
- M00000196401: Edb Oral Admin - 16.6 - 0 - 2 - Eric + Eric Turtle Brownie Bites

Product and Dispensary Metrics

- Retail units delivered to dispensaries: 1850
- Number of patients that purchased product: 389
- Number of units dispensed to patients: 602
- Returns: 220

Patient Adverse Events

- No reports of adverse events were received.

## V. Conclusion

The MMCP suspended sales and recalled previous sales of Beneleaves Eric + Eric Turtle Brownie Bites to investigate reports of visible mold on these products. In follow-up laboratory testing, yeast was detected on some samples of the product.

In coordination with the Department, Beneleaves submitted the products for additional testing and performed an internal investigation, including environmental and packaging testing. Additionally, Beneleaves developed a corrective action plan and updated its SOP with the intention of preventing similar product issues in the future.

[3] All medical marijuana products must have an assigned Product ID to be accepted by a dispensary and to enable submission of dispensation data to the Ohio Automated Rx Reporting System. This applies to each medical marijuana strain and medical marijuana form and dose. The assignment of a Product ID is to ensure that only products in compliance with MMCP regulations are available to patients and their caregivers.

**ATTACHMENT A**

## OHIO MEDICAL MARIJUANA CONTROL PROGRAM
## MANDATORY PRODUCT RECALL - 8/12/21

**TOPIC:** Mandatory Product Recall

**ISSUE:** The Ohio Medical Marijuana Control Program (MMCP) is issuing a mandatory product recall on edible product sold to dispensaries by processor, Beneleaves Limited. This recall is being initiated by the MMCP after receiving a report of mold. The MMCP is investigating this matter and will issue an executive summary at the conclusion of the investigation.

**AFFECTED PRODUCTS:**

**Product Name:**

- Eric + Eric Turtle Brownie Bites

**Available for Purchase:** Beginning June 22, 2021 - Present

**Products Purchased from:** Bloom Medicinal (Columbus, Painesville locations), Columbia Care (Dayton, Marietta locations), Firelands Scientific (Huron), Ohio Provisions (Carroll), Pure Ohio Wellness (London), RISE (Cleveland, Lorain, Toledo locations), Strawberry Fields (Columbus), Sunnyside (Chillicothe, Cincinnati, Marion, Newark locations), Terrasana (Columbus, Fremont, Garfield Heights, Springfield locations), ZenLeaf (Cincinnati)

**Processor Name:** Beneleaves Limited

**Product ID:**

- M00000174921: Edb Oral Admin - 16.6 - 0 - 2 - Eric + Eric Turtle Brownie Bites
- M00000196401: Edb Oral Admin - 16.6 - 0 - 2 - Eric + Eric Turtle Brownie Bites

**No reports of adverse reactions for this product have been reported to the MMCP at this time.**

***Patients who have purchased the recalled product should stop using it.*** *All unused product should be returned to the dispensary where purchased. Returned products will not count toward a patient's 90-day possession limit. For more information on returns, please contact the dispensary where the product was purchased.*

*Anyone who thinks that they may be experiencing serious or life-threatening issues should seek immediate medical attention. Patients are reminded that any adverse reactions should be reported to the MMCP toll-free helpline (1-833-464-6627).*