



## **EXECUTIVE SUMMARY:**

### **Recall of Galenas, LLC Blueberry Cookies Flower & Blueberry Cookies Shake**

February 25, 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). Galenas, LLC (Galenas), located in Akron, Ohio, is licensed as a level two cultivator by the Ohio Department of Commerce. On December 6, 2021, the MMCP issued a mandatory recall<sup>1</sup> for flower and shake sold by Galenas. This recall notified the public that the MMCP received reports from dispensaries of foreign matter (possibly plastic) within the packaging. 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. Galenas holds a cultivator license to grow and sell medical marijuana to processors and dispensaries.

Licensed cultivators grow medical marijuana and are required to track the inventory in MMCP's seed-to-sale inventory tracking system, Metrc. This system tracks the medical marijuana product as it grows, is tested, and potentially manufactured. The plant material is required to be tested after it is harvested but before it is transferred to a processor or dispensary. After the required testing is performed and the plant material passes the required analysis, it can then be transferred to a processor for manufacturing or sold to a dispensary.

The medical marijuana subject to this recall passed all required testing. Small plastic flakes later discovered in some of the flower and shake were determined to have come from the plastic bags used for packaging.

#### **III. Recall**

On December 6, 2021, the MMCP received a report from a dispensary of possible mold in Galenas Blueberry Cookies Flower and Blueberry Cookies Shake. After further investigation by the MMCP, Galenas representatives, and dispensary staff, it was determined that the contamination was not mold but small flakes of plastic, which fell off the plastic bags used for packaging.

The Department of Commerce MMCP, in coordination with the Ohio Board of Pharmacy, on December 6<sup>th</sup> issued a mandatory recall on the affected flower and shake, placed an administrative hold at the cultivator, and quarantined the packages at the dispensary so they could not be sold to patients.

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<sup>1</sup> See Attachment A

The MMCP directed Galenas to pick up the products from the affected dispensaries and submit samples for testing. On February 2, 2022, North Coast Testing Laboratory randomly selected samples of the recalled medical marijuana for testing. The lab reported on February 7, 2022, that the flower and shake passed all required testing.

Following conversations with its supplier of the plastic bags used for packaging, Galenas reported that the material found in some of the packages is called “zipper fluff” and it is a remnant of the bag manufacturing process. The material should have been removed by the bag manufacturer. The plastic flakes, or “zipper fluff,” material is non-toxic.

The MMCP subsequently permitted Galenas to sell the flower and shake only to a processor to be used in the manufacture of medical marijuana products.

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

- Identified all products located at the cultivator and dispensaries that were affected by the recall
- Communicated to patients that recalled products may be returned to dispensaries
- Required Galenas to collect all unsold products located at dispensaries
- Required Galenas to submit to additional testing
- Required product returned by patients to be destroyed at the return dispensary location

**Galenas 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
- Submitted to additional testing required by the Department
- Conducted an internal investigation
- Worked with the plastic bag manufacturer to determine the source of the issue

#### **IV. Recall Metrics**

Products Recalled

- Blueberry Cookies Flower & Blueberry Cookies Shake

Product IDs<sup>2</sup> Recalled

- M00000267014: Tier 1 Vap-Hybrid-17.9-0.1-BLUEBERRY COOKIE SHAKE-2.83
- M00000267018: Tier 1 Vap-Hybrid-17.9-0.1- BLUEBERRY COOKIE SHAKE-14.15
- M00000266708: Tier 2 Vap-Hybrid-26.7-0.1- BLUEBERRY COOKIE SHAKE-5.66
- M00000266711: Tier 2 Vap-Hybrid-26.7-0.1- BLUEBERRY COOKIE SHAKE-14.15
- M00000267001: Tier 2 Vap-Hybrid-31.5-0.1-BLUEBERRY COOKIE-2.83
- M00000267002: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-5.66
- M00000267003: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-8.49

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<sup>2</sup> 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.

- M00000267004: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-11.32
- M00000267005: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-14.15

#### Product and Dispensary Metrics

- Retail units delivered to dispensaries: 5,114
- Number of patients that purchased product: 1,088
- Number of units dispensed to patients: 1,379
- Returns: 272
- Number of dispensaries impacted by recall: 38

#### Patient Adverse Events

- No reports of adverse events were received.

### **V. Conclusion**

After receiving reports from dispensaries of possible mold contamination, the MMCP suspended sales of all Galenas Blueberry Cookies Flower and Blueberry Cookies Shake to investigate. These products had previously passed all required testing prior to packaging. It was determined that the plastic packaging was the source of the contaminant.

In coordination with the Department, Galenas submitted the medical marijuana for additional testing, which it passed, and performed an internal investigation. Additionally, Galenas spoke with the manufacturer of the plastic bags used for packaging of the medical marijuana subject to this recall and determined the source of the plastic flakes as a remnant of the manufacturing process that should have been removed by the manufacturer prior to distribution to Galenas. Galenas has cooperated with the recall investigation with the intention of preventing similar product issues in the future.

**ATTACHMENT A**



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**OHIO MEDICAL MARIJUANA CONTROL PROGRAM  
MANDATORY PRODUCT RECALL – 12/06/21**

**TOPIC:** Mandatory Product Recall

**ISSUE:** The Ohio Medical Marijuana Control Program (MMCP) is issuing a mandatory product recall on plant material products sold to dispensaries by cultivator, Galenas, LLC. This recall is being initiated by the MMCP because the MMCP received reports from dispensaries of foreign matter (possibly plastic) within the packaging. The MMCP is continuing to investigate and will issue an executive summary at the conclusion of the investigation.

**AFFECTED PRODUCT:**

**Product Name:** Blueberry Cookies Flower & Blueberry Cookies Shake

**Purchase Dates:** Beginning October 14, 2021 – Present

**Cultivator Name:** Galenas, LLC

**Product ID:**

- M00000267014: Tier 1 Vap-Hybrid-17.9-0.1-BLUEBERRY COOKIE SHAKE-2.83
- M00000267018: Tier 1 Vap-Hybrid-17.9-0.1- BLUEBERRY COOKIE SHAKE-14.15
- M00000266708: Tier 2 Vap-Hybrid-26.7-0.1- BLUEBERRY COOKIE SHAKE-5.66
- M00000266711: Tier 2 Vap-Hybrid-26.7-0.1- BLUEBERRY COOKIE SHAKE-14.15
- M00000267001: Tier 2 Vap-Hybrid-31.5-0.1-BLUEBERRY COOKIE-2.83
- M00000267002: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-5.66
- M00000267003: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-8.49
- M00000267004: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-11.32
- M00000267005: Tier 2 Vap-Hybrid-31.5-0.1- BLUEBERRY COOKIE-14.15

**Products Purchased from:**

- Bloom Medicinals - Akron
- Bloom Medicinals - Columbus
- Bloom Medicinals - Maumee
- Bloom Medicinals - Painesville

Bloom Medicinals - Seven Mile  
The Botanist - Akron  
The Botanist - Canton  
The Botanist - Cleveland  
The Botanist - Columbus  
The Botanist - Wickliffe  
Columbia Care - Dayton  
Columbia Care - Logan  
Columbia Care - Marietta  
Columbia Care - Monroe  
FRX Health - East Liverpool  
Gleaf Medical Cannabis - Warren  
Herbology - Cuyahoga Falls  
Herbology - Newark  
Leaf Relief - Youngstown  
Ohio Cannabis Company - Coshocton  
Ohio Provisions - Carroll  
Ohio Valley Natural Relief - Wintersville  
Pure Ohio Wellness - Dayton  
Pure Ohio Wellness - London  
Rise - Cleveland  
Rise - Lakewood  
Rise - Lakewood  
Rise - Lorain  
Rise - Toledo  
Strawberry Fields - Columbus  
Sunnyside - Chillicothe  
Sunnyside - Cincinnati  
Sunnyside - Marion  
Sunnyside - Newark  
Sunnyside - Wintersville  
Verilife - Cincinnati  
Verilife - Hillsboro  
Verilife - Wapakoneta

**No reports of adverse reactions for this product have been reported to the MMCP at this time. The plant material subject to this recall previously passed all required testing.**

***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).*

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