Medical Marijuana Advisory Board Meeting

Wednesday, January 24, 2024

10:30 a.m. – 12:30 p.m.

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MMAB Agenda

I. Call meeting to order, announcements and roll call
II. Approval of the previous meeting's minutes – November 15, 2023
III. Program Update
IV. Old Business
    a. Board assignments, updates and requested agenda topics:
        i. Subcommittee updates:
            - ***Medical Review*** – Dr. Geith Shahoud, Subcommittee Chair
                - Discussion of SMC Application for CH 20 Research Application
            - ***Patient and Caregiver*** – Diana Briggs, Subcommittee Chair
            - ***Regulatory Review*** – Christine Roussel, Pharm.D., R.Ph., Subcommittee Chair
            - ***Medical Research*** – Bhavini Patel, Subcommittee Chair
                - Discussion of Organic Remedies' presentation regarding the findings of the research initiative
                - American Society for Testing and Materials (ASTM) – Overview
        ii. Protections for healthcare provider administration of state regulated medical marijuana products

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MMAB Agenda

V. New Business
   i. Discussion of SMC Application for CH 20 Research Application
   ii. Addition of Nursing Practitioners to the list of practitioners who can certify Medical Marijuana Patients in Pennsylvania
   iii. Submission of report regarding addition of nursing practitioners to the list of practitioners who can certify medical marijuana patients in Pennsylvania

VI. Additional Discussion/Q&A

VII. Adjournment

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Medical Marijuana Program Update

Program

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Medical Marijuana Program Updates

- CANNRA conference
- Act 63
- Currently Underserved Counties
- Program Metrics

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CANNRA

- CANNRA conference was hosted on December 4-6, 2023.
- Attended by approximately 39 states, Canada, and FDA,
- Valuable cannabis industry topics including trends, challenges, wins.

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Act 63

- Act 63 of 2023 becomes effective in April 2024.
- Qualifying "independent grower/processors" may apply for and be issued 1 dispensary permit and qualifying "independent dispensaries" may apply for and be issued 1 grower/processor permit
- In preparation for additional dispensary permit applications and in keeping with the Office's commitment to patient access, the Office is identifying the counties that are currently underserved by the dispensary facilities.

Currently Underserved Counties

13 counties deemed underserved

- Adams
- Beaver
- Bedford
- Bradford
- Clinton
- Fayette
- Juniata
- Northumberland
- Pike
- Schuylkill
- Tioga
- Venango
- Warren

How were these counties identified?

- Average distance traveled per order (with minimum volume of orders)
- Current population or certification density per dispensary

Note that the criteria and results change often as the market matures, more dispensaries open, certifications change, etc.

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Program Metrics as of 1/12/2024

436,018 Active Patient Certifications

1,920 Approved Practitioners

9,286 Active Carded Caregivers

177 Operational Dispensaries

$400,587.09 MMAP Phase 3 Financial Benefit Given

33 Operational Grower/Processors

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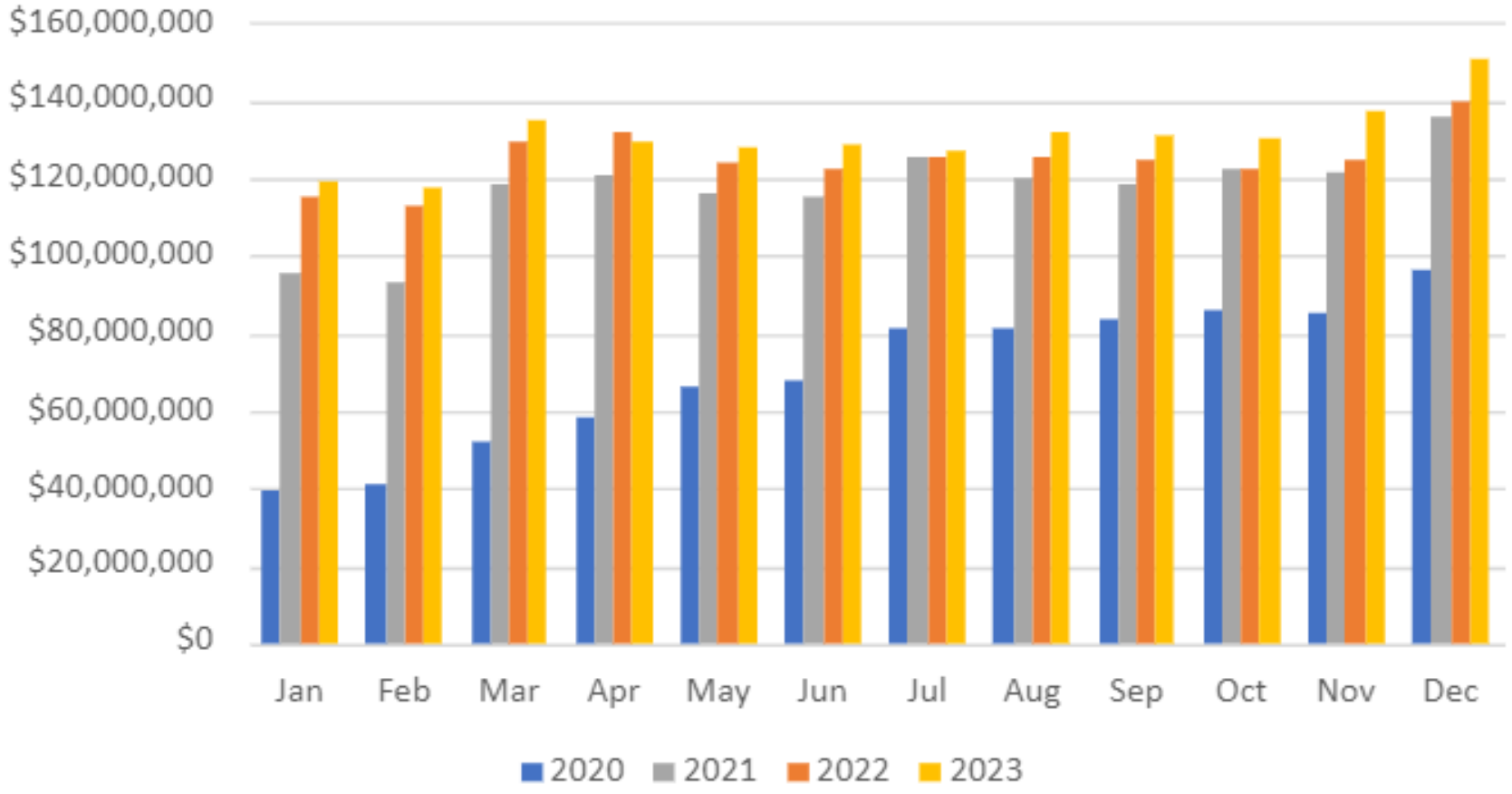
Medical Marijuana Program Update

Dispensary Sales by Month Since Jan 2020



$5.6 Billion Sales Program-to-Date

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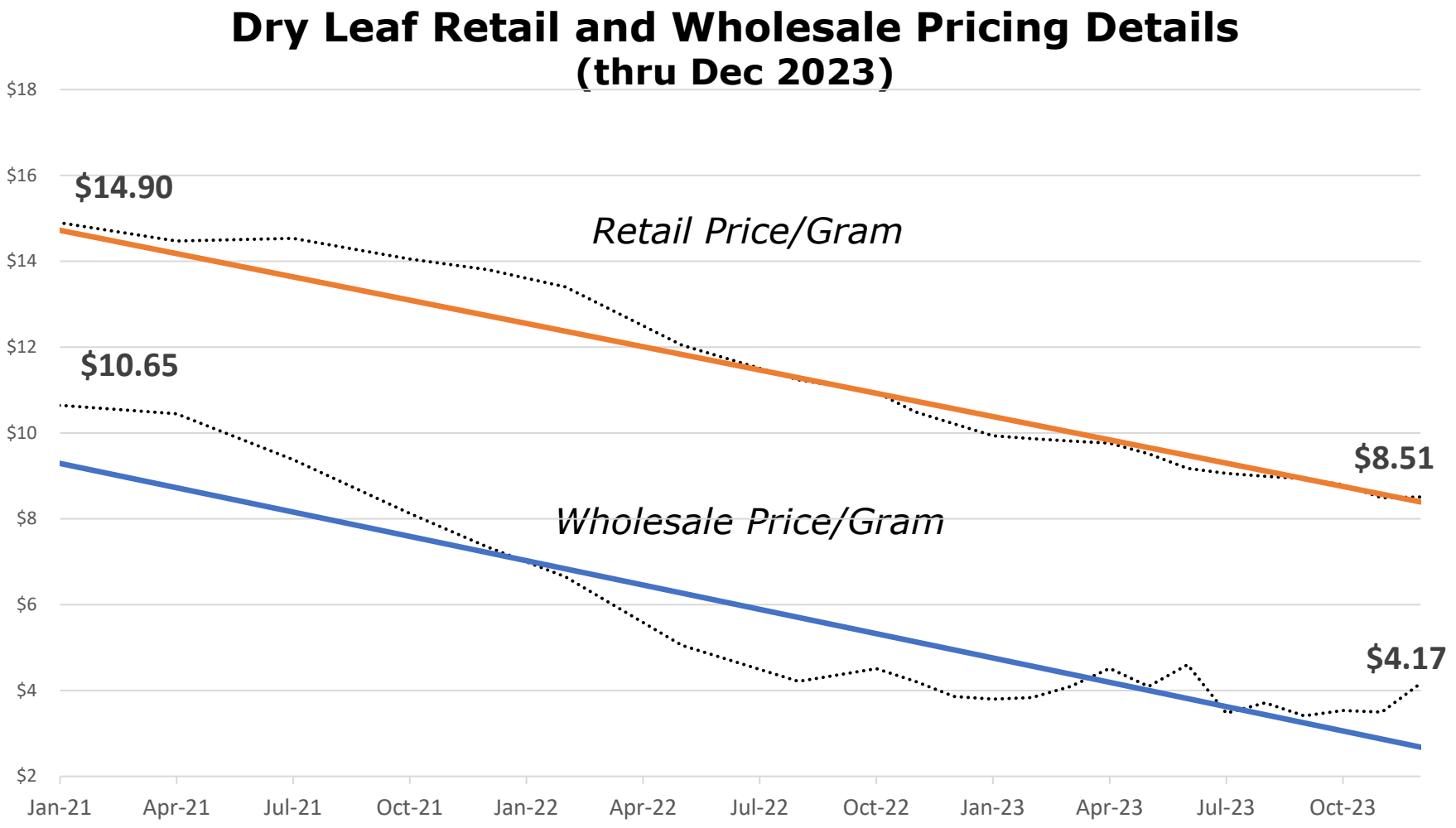
Medical Marijuana Program Update



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Old Business

I. Old Business
   a. Board assignments, updates and requested agenda topics:
      i. Subcommittee updates:
         - ***Medical Review*** – Vacant, Subcommittee Chair
            - Discussion of SMC Application for CH 20 Research Application
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         - ***Regulatory Review*** – Christine Roussel, Pharm.D., R.Ph., Subcommittee Chair
         - ***Medical Research*** – Bhavini Patel, Subcommittee Chair
            - Discussion of Organic Remedies' presentation regarding the findings of the research initiative
            - American Society for Testing and Materials (ASTM) – Overview

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An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock

June-Wells MR, Fochtman FW, Balin B, Petroski WP, Niesen D, Hauser E

OVERVIEW

What Will This Talk Cover:

~ Current State Regulations – Marijuana and Extract Testing

~ Impact of Crop Destruction on Business

~ Purpose and Goals of This Study

~ Overview of Organic Remedies Manufacturing Processes

~ Study Methodology

~ Study Findings

~ Conclusions

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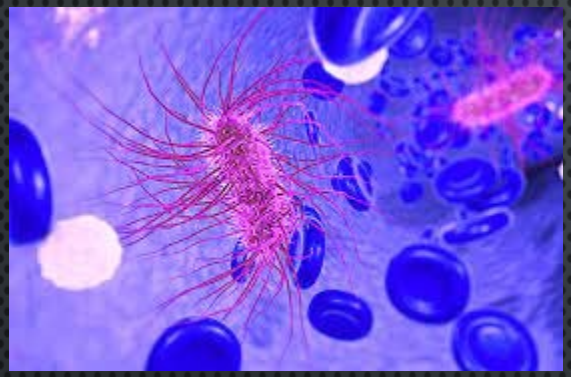
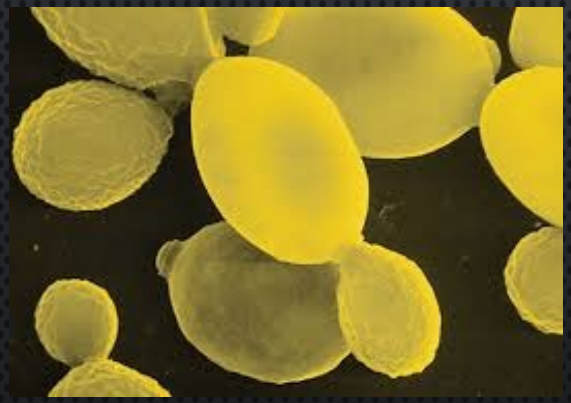
Current Pennsylvania Cannabis Microbial Regulations





~ Plant Material:

- ~ *Escherichia coli* – non-detect
- ~ *Salmonella spp.* – non-detect
- ~ Total aerobic bacteria – <10,000cfu/g
- ~ Total yeast and mold – <10,000cfu/g
- ~ Total enterobacteriaceae – <1,000cfu/g

~ Extracts:

- ~ *Escherichia coli* – non-detect
- ~ *Salmonella spp.* – non-detect
- ~ Total aerobic bacteria – <10,000cfu/g
- ~ Total yeast and mold – <1,000cfu/g
- ~ Total enterobacteriaceae – <100cfu/g

Notes:

~ Material that does not pass harvest testing in plant material phase can not be utilized in extraction.

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RAMIFICATION OF BATCH DESTRUCTION

~ Cost of goods (Flower Production)

~ Higher cost of products to patients

~ Lost Employment opportunities

~ Lost revenue

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STERILIZATION STUDY PURPOSE AND GOALS

~ **PURPOSE:** TO DETERMINE WHETHER ORGANIC REMEDIES INC.'S UNIDIRECTIONAL ASEPTIC MANUFACTURING PROCESS IS CAPABLE OF CREATING EXTRACTED RAW MATERIALS THAT ARE FREE OF MICROBIAL CONTAMINANTS AND THEIR METABOLITES WHEN CONTAMINATED FEED MATERIAL IS UTILIZED IN THE EXTRACTION PROCESS.

~ **GOALS:**

- ~ TO SHOW THAT EXTRACT MANUFACTURING PROTOCOLS CAN REMOVE/DEACTIVATE MICROBIAL CONTAMINATION PRESENT IN THE PARENT PLANT MATERIAL AND PRODUCE EXTRACTED RAW MATERIALS THAT MEET OR EXCEED PA REGULATIONS.
- ~ TO DETERMINE THE CRITICAL STEPS IN THE MANUFACTURING PROCESS THAT REMOVE MICROBIAL CONTAMINANTS AND THEIR METABOLITES THAT WERE PRESENT IN FEED MATERIAL.
- ~ TO EVALUATE THE SUITABILITY OF RAW MATERIALS PRODUCED FROM MICROBIAL CONTAMINATED FEED MATERIAL IN THE MANUFACTURING OF FINAL PRODUCTS FOR DISTRIBUTION.

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WHAT IS NOT INCLUDED IN THIS STUDY

~ This study does not make any suggestive comparisons of the PA regulatory framework to any other state in the Union.

~ This study does not evaluate the current regulatory framework as it applies to flower or extracted products.

~ This study is not a request to change the regulatory framework as it applies to the number of colony forming units allowed in final products of any type.

~ This study does not promote any form of remediation; this is a manufacturing study that focuses on the aseptic nature of the extraction process

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OVERVIEW OF ORGANIC REMEDIES MANUFACTURING PROCESSES

1) Hydrocarbon
2) Supercritical Carbon Dioxide

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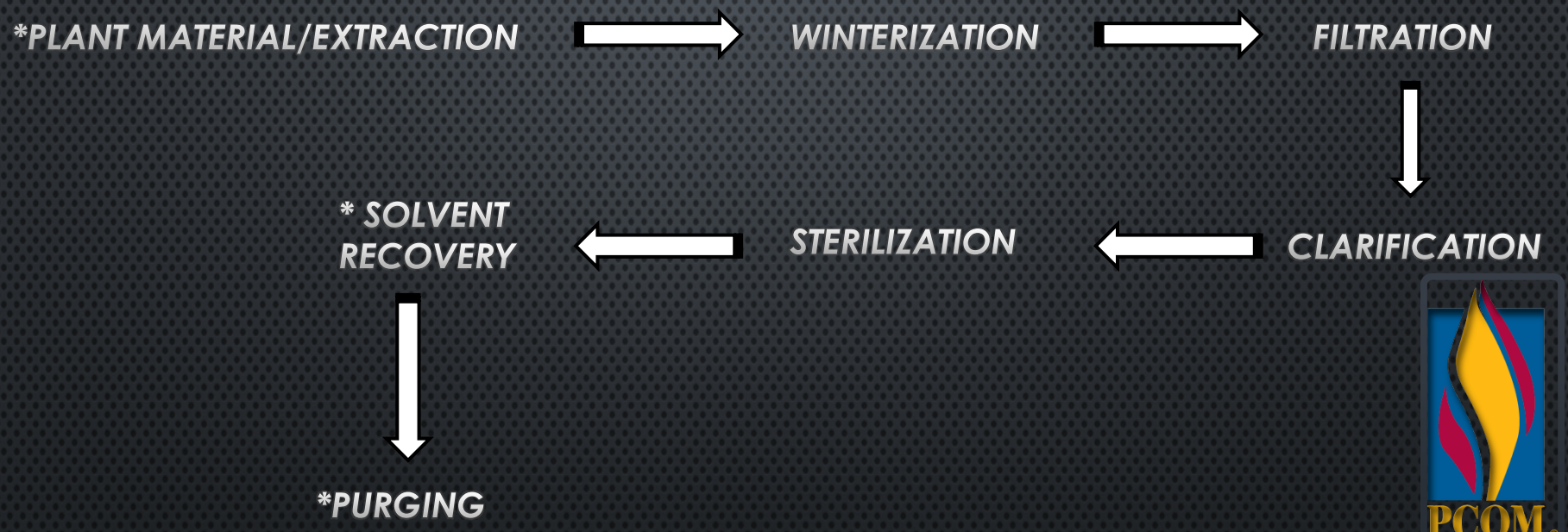
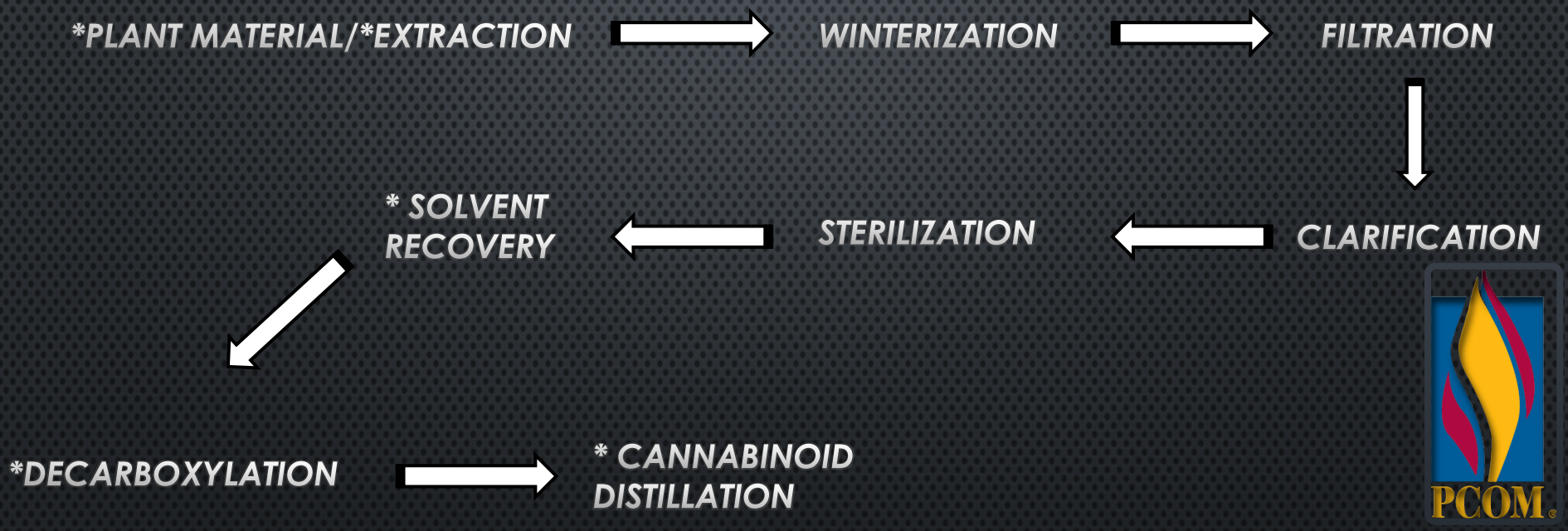
MANUFACTURING: HYDROCARBON PIPELINE



* Indicates sample collection during study

MANUFACTURING: CARBON DIOXIDE PIPELINE



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Plant Based Therapy ORGANIC REMEDIES

* Indicates sample collection during study

STUDY METHODOLOGY

~ Plant material and batch size
~ Replicates
~ Hydrocarbon Processing and Replicates
~ Carbon Dioxide Processing and Replicates
~ Statistical Design
~ Sample testing

HYPOTHETICAL OUTCOMES

Hypotheses:

- Extraction processes do not remove microbial activity during the extraction process (NULL).
- Linear or describable decrease of microbial load in extracts from beginning to end of manufacturing.
- Existence of a critical step where reduction of microbial load goes to zero.

ACTUAL OUTCOMES

Overview of Findings:

- Microbial activity found in plant material is not conveyed during the extraction process.
- A critical step for microbial removal/deactivation exists (extraction Phases, solvent independent)
  - Microbial load reduced to zero after the primary extraction phase for both technology types.
- This lack of microbial activity is maintained from the primary extraction phase through to final raw material production.
  - No metabolites or microbial activity were detected in any extract type (e.g., primary, essential oil, etc.)

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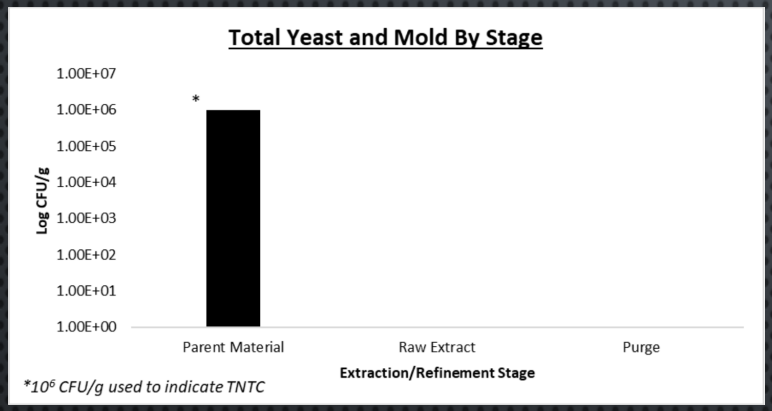
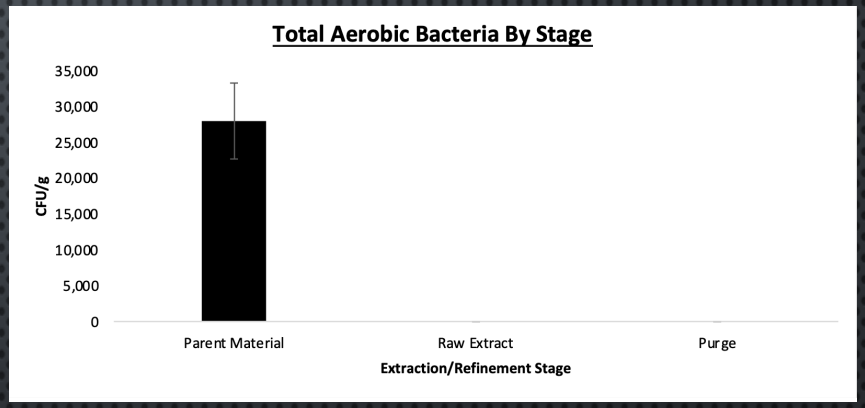
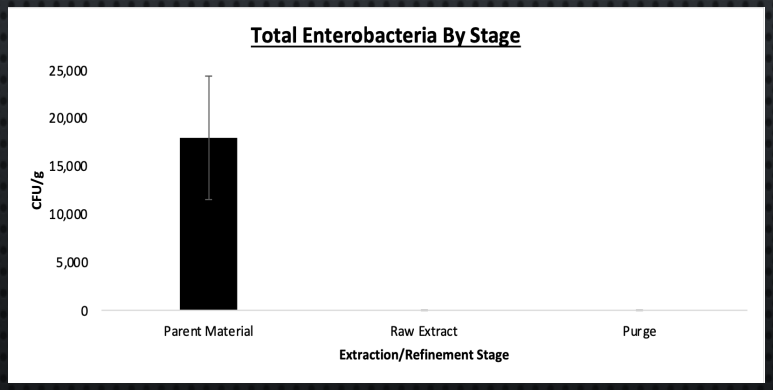
An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock

June-Wells MR[1*], Fochtman FW[2], Balin B[3], Petroski WP[1], Niesen D[4], and Hauser E[1]







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Hydrocarbon Pathway Sterilization Data

Stage	Strain	THC (%)*	CBD (%)*	TTl Can (%)	TTl Terp (%)	TYM cfu/g	TAB cfu/g	ENT cfu/g	*E. coli* cfu/g	*Salmonella spp.* cfu/g
Parent Material	Triangle Kush X Fruity Pebbles	14.98	0.00	17.27	1.28	TNTC	28000	17975	0	0
Extraction		**THC (%)***	**CBD (%)***	**TTl Can (%)**	**TTl Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
HE0088-1		66.92	0	76.70	6.46	0	0	0	0	0
HE0088-2		66.55	0	76.37	6.83	0	0	0	0	0
HE0088-3	Triangle Kush X Fruity Pebbles	67.21	0	77.00	7.00	0	0	0	0	0
HE0088-4		66.89	0	76.82	6.93	0	0	0	0	0
HE0088-5		67.31	0	77.08	7.06	0	0	0	0	0
Essential Oil		**THC (%)***	**CBD (%)***	**TTl Can (%)**	**TTl Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
SH0069-1		71.43	0	81.80	6.40	0	0	0	0	0
SH0069-2		70.92	0	81.16	6.39	0	0	0	0	0
SH0069-3	Triangle Kush X Fruity Pebbles	72.18	0	82.81	6.31	0	0	0	0	0
SH0069-4		71.82	0	82.22	6.25	0	0	0	0	0
SH0069-5		71.47	0	81.97	6.51	0	0	0	0	0

*indicates percentages calculated from the conversion of the acid-form percentages plus the percentage of the neutral form.

Converted % = (0.87 *Acid Form %)+ Neutral Form %

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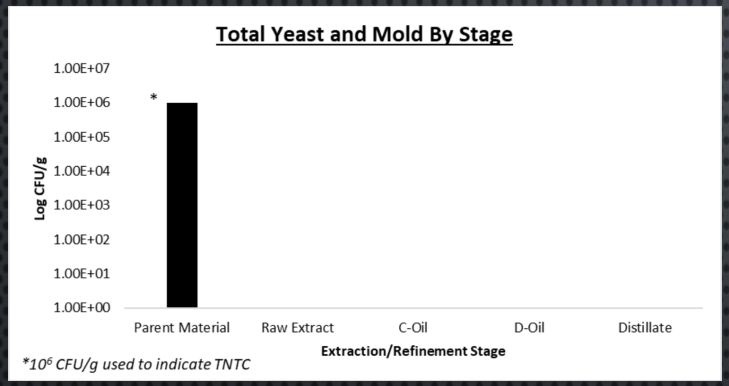
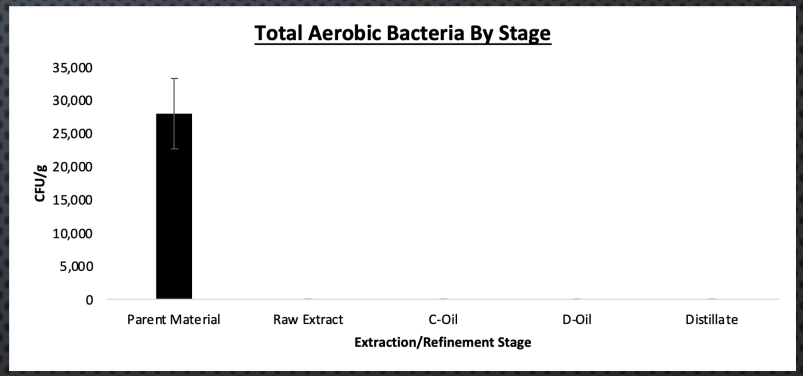
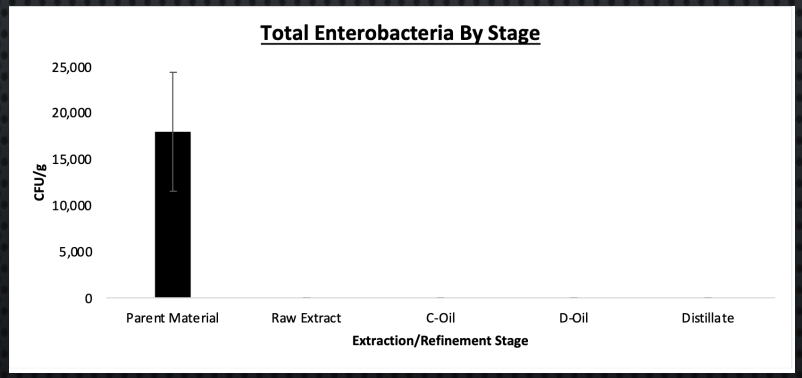






Carbon Dioxide Pathway Sterilization Data

Stage	Strain	THC (%)*	CBD (%)*	TII Can (%)	TII Terp (%)	TYM cfu/g	TAB cfu/g	ENT cfu/g	*E. coli* cfu/g	*Salmonella spp.* cfu/g
Parent Material	Triangle Kush X Fruity Pebbles	14.98	0.00	17.27	1.28	TNTC	28000	17975	0	0
Extraction		**THC (%)***	**CBD (%)***	**TII Can (%)**	**TII Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
EX0433A	Triangle Kush X Fruity Pebbles	69.45	0	78.15	0.44	0	0	0	0	0
EX0433B		48.96	0	55.71	7.97	0	0	0	0	0
EX0434A		68.51	0	77.27	0.25	0	0	0	0	0
EX0434B		48.87	0	55.59	7.72	0	0	0	0	0
EX0435A		69.33	0	78.48	0.33	0	0	0	0	0
EX0435B		45.76	0	52.09	10.14	0	0	0	0	0
EX0436A		66.85	0	75.69	0.38	0	0	0	0	0
EX0436B		44.69	0	50.74	11.83	0	0	0	0	0
EX0437A		68.52	0	77.01	0.31	0	0	0	0	0
EX0437B		45.83	0	51.93	9.48	0	0	0	0	0
Essential Oil		**THC (%)***	**CBD (%)***	**TII Can (%)**	**TII Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
C0128-1	Triangle Kush X Fruity Pebbles	68.20	0	76.79	1.34	0	0	0	0	0
C0128-2		68.19	0	76.98	1.45	0	0	0	0	0
C0128-3		68.50	0	77.35	1.51	0	0	0	0	0
C0128-4		68.12	0	76.93	1.45	0	0	0	0	0
C0128-5		69.52	0	78.89	1.46	0	0	0	0	0
Decarboxylated Oil		**THC (%)***	**CBD (%)***	**TII Can (%)**	**TII Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
D0142-1	Triangle Kush X Fruity Pebbles	72.32	0	0.25	0.25	0	0	0	0	0
D1042-2		71.24	0	0.28	0.28	0	0	0	0	0
D0142-3		72.55	0	0.24	0.24	0	0	0	0	0
D0142-4		71.52	0	0.24	0.24	0	0	0	0	0
D0142-5		73.66	0	0.24	0.24	0	0	0	0	0
Distilled Oil		**THC (%)***	**CBD (%)***	**TII Can (%)**	**TII Terp (%)**	**TYM cfu/g**	**TAB cfu/g**	**ENT cfu/g**	***E. coli* cfu/g**	***Salmonella spp.* cfu/g**
ID0128-1	Triangle Kush X Fruity Pebbles	85.60	0	93.90	0.00	0	0	0	0	0
ID0128-2		85.69	0	93.87	0.00	0	0	0	0	0
ID0128-3		85.46	0	93.56	0.05	0	0	0	0	0
ID0128-4		84.98	0	92.98	0.05	0	0	0	0	0
ID0128-5		85.84	0	94.19	0.05	0	0	0	0	0

***indicates percentages calculated from the conversion of the acid-form percentages plus the percentage of the neutral form.**

Converted % = (0.87*Acid Form %)+ Neutral Form %

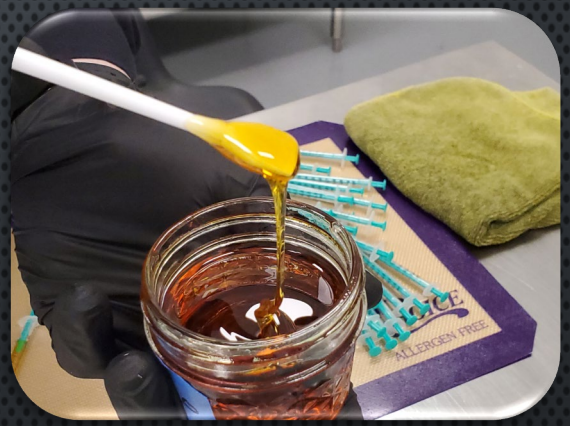
STUDY FINDINGS

~ Organic Remedies Inc. found through this research initiative that the infrastructure deployed at the manufacturing facility to comply with CFR21's definition of unidirectional aseptic processing was highly efficacious for the removal of biological contaminants and their metabolites during the extraction manufacturing process.

> ~ The critical phase for removal of biological contaminants and their metabolites was the primary extraction phase.
>
> ~ All other steps in the process maintained or enhanced the capture of biological contaminants and their metabolites.

~ We conclude that Organic Remedies Inc.'s manufacturing laboratory's infrastructure and unidirectional aseptic processing design results in raw materials that exceed the regulatory limits set forth by The State of Pennsylvania.

~ Finally, we conclude that there is little need for testing prior to extract manufacturing due to the findings herein and because of the regulatory requirement for final product testing prior to release to the medical marijuana patients of Pennsylvania.



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THANK YOU

MARK JUNE-WELLS, PH.D.

CHIEF SCIENCE OFFICER – ORGANIC REMEDIES INC.

M.JUNEWELLS@ORGANICREMEDIESPA.COM

S3 Collective

STANDARDS • SCIENCE • SAFETY

David Vaillencourt, M.Sc.

January 24, 2024 – Pennsylvania Medical Marijuana Advisory Board

Overview

- Products and a marketplace that is **safe**, **affordable**, and **trusted**
- What is ASTM International?
- Why do we have industry Landscape of current microbial/bioburden requirements for cannabis
- History of public health crises and regulations
- Use of decontamination and kill steps
- Risks
- Solutions

ASTM INTERNATIONAL
Helping our world work better

Established in 1898
147 Committees & 12,500 standards
30,000 + volunteer members
135 countries
Development and delivery of information made uncomplicated
A common sense approach: industry driven
Market relevant globally

Committee D37 on Cannabis – Approved by the Board June 2017

How are standards used? Cited in contracts, referenced in codes, regulations, and laws.

Designation: D8439 – 22
Standard Specification for
Medicinal-use Cannabis Inflorescence

Designation: D8282 – 19
Standard Practice for
Laboratory Test Method Validation and Method Development[1]

Standards and U.S. Legal and Policy Framework

National Technology Transfer and Advancement Act of 1995 (NTTAA)

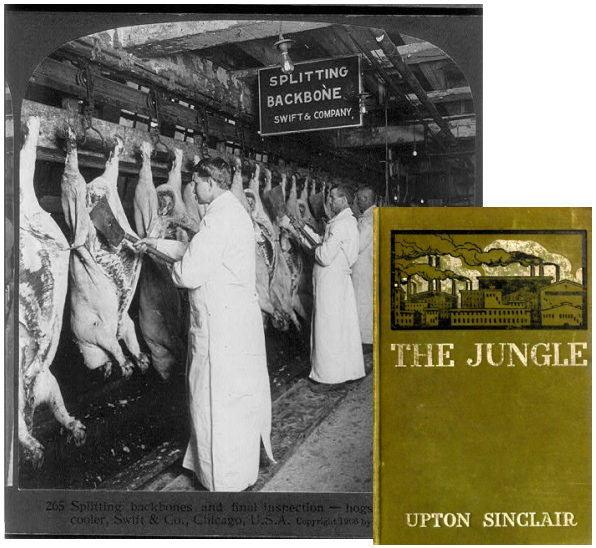
- Requires federal government agencies to use standards developed by voluntary consensus standards organization when possible
- Encourages federal government agencies to participate in standards development organizations

OMB Circular No. A-119

- Reinforces goals of National Technology Transfer and Advancement Act
- Discourages federal agencies from using government-unique standards

"A voluntary consensus standards body is defined by the following attributes: (i) Openness. (ii) Balance of interest. (iii) Due process. (vi) An appeals process. (v) Consensus"

Why public health regulations?



2012 Framingham, MA

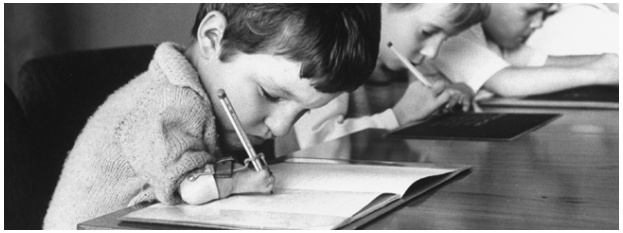
New England Compounding Center (NECC)

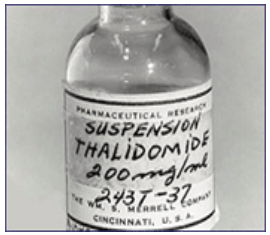
Contaminated steroid injection containing fungal meningitis

- 800 Sickened
- 76 deaths
- 14 NECC employees federally charged
- $200M settlement

1937 Sulfanilamide poisoning

- 240 gallons
- 100 deaths in 15 states

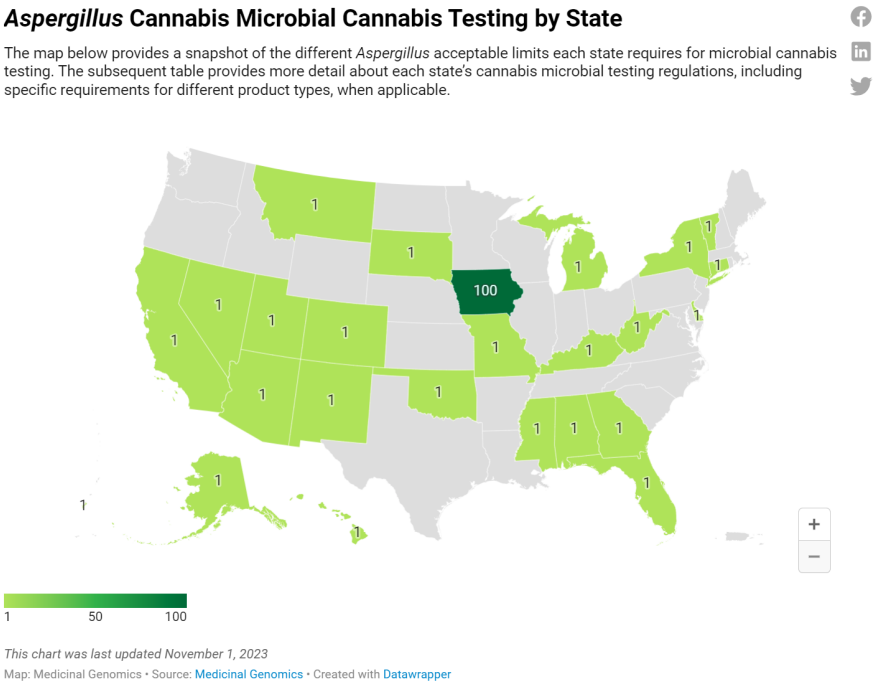




1957 Thalidomide

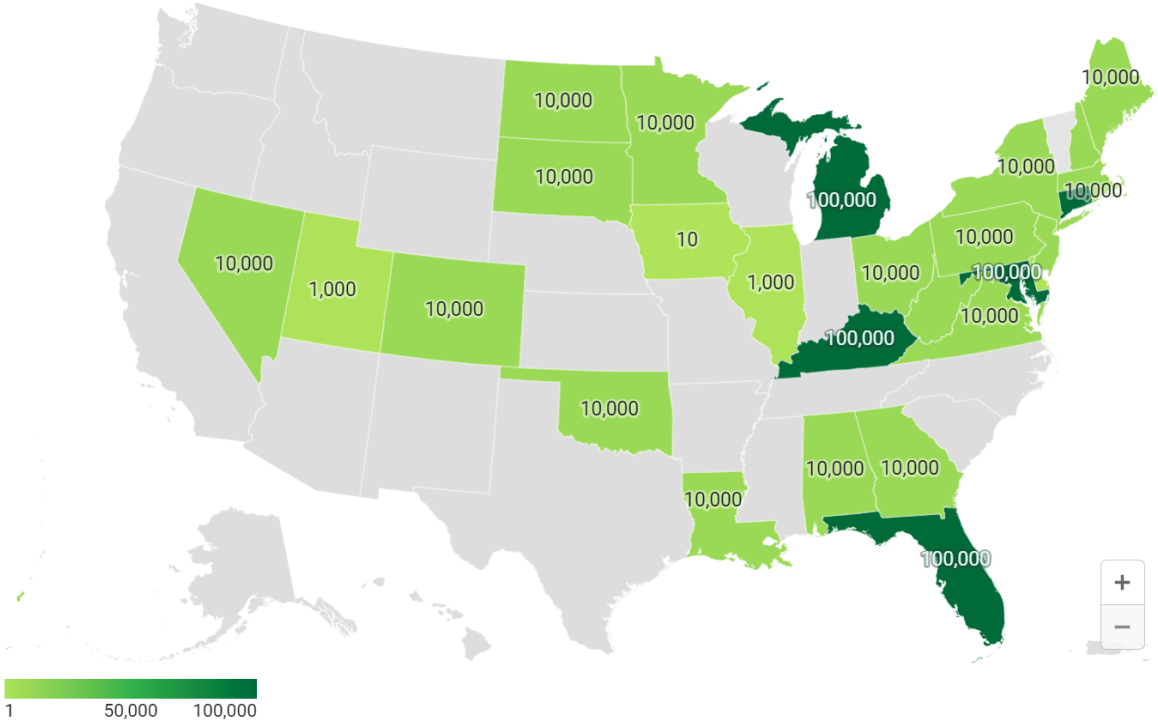
- 10,000 worldwide cases
- 50% mortality rate

Aspergillus



Total Yeast and Mold Microbial Cannabis Testing By State

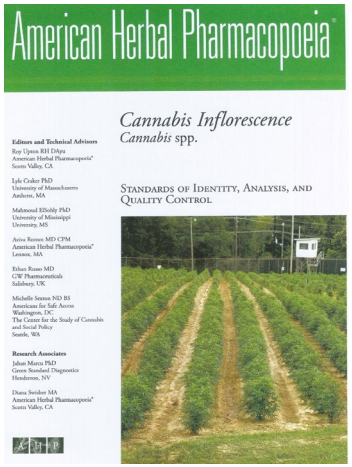
The map below provides a snapshot of the different Total Yeast and Mold acceptable limits each state requires for microbial cannabis testing. The subsequent table provides more detail about each state's cannabis microbial testing regulations, including specific requirements for different product types, when applicable.



This chart was last updated November 1, 2023

Map: Medicinal Genomics • Source: Medicinal Genomics • Created with Datawrapper

Cannabis and Microbial Limits



ASTM INTERNATIONAL

Designation: D8439 – 22

Standard Specification for Medicinal-use Cannabis Inflorescence

JOURNAL OF NATURAL PRODUCTS

pubs.acs.org/jnp Review

Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes

Nandakumara D. Sarma,* Andrew Waye, Mahmoud A. ElSohly, Paula N. Brown, Sytze Elzinga, Holly E. Johnson, Robin J. Marles, Jeremy E. Melanson, Ethan Russo, Lawrence Deyton, Christopher Hudalla, Gordon A. Vrdoljak, Joshua H. Wurzer, Ikhlas A. Khan, Nam-Cheol Kim, and Gabriel I. Giancaspro

Broader perspective – Other industries

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2017–N–6924]

RIN 0910–AH47

Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule repealing a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation will mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is taking this action because the irradiation regulation is out of date and unnecessary.

DATES: This rule is effective January 15, 2020.

ADDRESSES: For access to the docket to

Potential Solutions

- Remediation – Product type change (e.g. plant – extract)
- Decontamination – After testing fail
- Microbial control step

"Microbial Control Step" means a post-harvest process that is intended to reduce the presence of microbial contaminant(s) in a Harvest Batch or Production Batch that is performed prior to testing consistently on all Harvest Batches or Production Batches of a particular type, strain, or intended use, as documented in the Regulated Marijuana Business's standard operating procedures.

ASTM D8250-19 ⓘ

Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products

S3 Collective

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Thank you!

David Vaillencourt
David@s3collective.org

Old Business - DISCUSSION

I. Old Business

a. Board assignments, updates and requested agenda topics:

- ***Medical Research*** – Bhavini Patel, Subcommittee Chair
  - Discussion of Organic Remedies' presentation regarding the findings of the research initiative
  - American Society for Testing and Materials (ASTM) – Overview

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Old Business - continued

I. Old Business

ii. Protections for healthcare provider administration of state regulated medical marijuana products

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New Business

i. Discussion of SMC Application for Chapter 20 Research

ii. Addition of Nursing Practitioners to the list of practitioners who can certify Medical Marijuana Patients in Pennsylvania

iii. Submission of report regarding addition of nursing practitioners to the list of practitioners who can certify medical marijuana patients in Pennsylvania

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Additional Discussion/Q&A

- Other topics for discussion?

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Adjournment

- Next Meeting is **March 20, 2024**.

- 2024 Dates:
  - January 24
  - March 20
  - May 22
  - July 24
  - September 18
  - November 13

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