

**Daye**

# FDA Public Hearing

## Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds

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hemp tampons  
CBD-infused  
plastic-free

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CEO

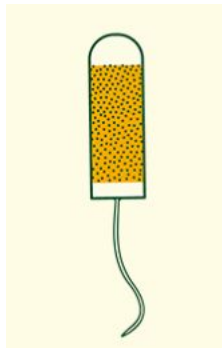
## Overview

1. Product Description
2. Vaginally Administered CBD
3. Topical CBD
3. Quality Standards in Supply Chain
4. Quality Standards in Manufacturing
5. Shelf-life and Product Stability
6. Labelling
7. Continuous Market Feedback
8. Research Completed
9. Research Pipeline

## Product Description

### CBD-Infused Tampons

Novel extraction method  
to ensure our CBD is  
100% THC-free



### Cottonized Hemp Fibre

To replace petrol-derived  
plastic

Improved absorption



### Tampons manufactured as medical devices

Pharmaceutical-grade  
sanitisation and clean  
room coating

Reduces risk of TSS



## Vaginally Administered CBD

### Advantages

Binds to epithelial cannabinoid receptors  
Unaffected by nausea/vomiting  
Local site of action

### Disadvantages

Social taboo

## Topical CBD

### Local Cosmetic Benefits

Anti-inflammatory

Improvement in skin barrier functions

Relief of noxious stimuli

# Quality Standards in Supply Chain

## Exclusivity Agreements

Consistency of end product

## Each Batch Tested

Ensure no Candida, E. coli, Staph, TAMC, TYMC, Heavy metals

## Supplier Conformity Agreements

Ensuring supplier liability in case of poor product quality

# Quality Standards in Manufacturing

**Medical-grade  
Machine  
Components**

**Coating in  
ISO8-certified Clean  
Rooms**

**Sanitization using  
Gamma Rays**

# Shelf-life and Stability Testing

**Manufacturing in Humidity and Temperature controlled environment**

**Accelerated Shelf-life Testing Conducted on Finished Products and Raw Materials**

**Medical-grade Tampon Wrappers and Compostable Plastic Pouches**



## Labelling

### **Clear Indications and Contraindications on Packaging**

Risk of TSS and risk of CBD allergies

### **Post-Consumer Marketing**

Compliant with FDA recommendations  
“CBD tampons” “soothing” “lubricating”

## Dosing

### Extensive Literature Review

Trial of 100mg and 150mg with volunteers

### Plan for Future Adjustment

Volunteer trials

Self-reported outcomes

## Research Completed

### Vaginal Microbiome

Staph aureus  
suppression  
Protects against TSS

### Vaginal Epithelium

No irritation  
pH balancing

### Volunteer Trials

Well-tolerated  
Effective

## Research Pipeline

### Double-Blind Multicentre RCT

CBD tampons for  
dysmenorrhea  
80 patients  
FDA/EMA-approved  
facility

### Further Preclinical Trials

Rabbit/sheep models  
Assess sensitivity,  
irritation, cytotoxicity,  
etc.

### Vaginal Microbiome

qPCR  
Effect over 3 cycles  
on microbial  
populations

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Thank you!

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