



By Joe Girardo



How Regulatory Oversight Protects CBD Consumers

INTRODUCTION

As the popularity of hemp-derived Cannabidiol (CBD) products continues to rise, both consumers and companies seeking reliable suppliers face a growing challenge: identifying safe, effective, and high-quality products amidst a sea of questionable claims and inconsistent manufacturing standards. Consumers and potential partners may rely on Certificates of Analysis (COAs) as a tool for assessing quality and safety, however, not all COAs are created equal, and this may cause them to unknowingly place their trust in products that do not meet the stringent standards required for pharmaceutical-grade manufacturing.

This white paper aims to educate both consumers and prospective customers on the risks associated with nutraceutical-grade and consumable hemp products and explain how Benuvia's pharmaceutical-grade APIs and drug products set the benchmark for safety, quality, and reliability.

BENUVIA IS NOT A NUTRACEUTICAL OR FOOD PRODUCT MANUFACTURER

It is important to note that Benuvia is not a nutraceutical or food manufacturer. We are a pharmaceutical manufacturer of active pharmaceutical ingredients (APIs) and finished drug products. Our operations adhere to the highest and most stringent regulatory standards in the industry. Pharmaceutical manufacturing is held to a level of oversight that ensures the utmost safety, quality, and consistency; a level that far surpasses the requirements for nutraceutical and food-grade products.

Joe Girardo, has over 10 years of experience in the pharmaceutical industry overseeing supply chain management, business development, and project management. As Director of Commercial Operations, Joe plays a pivotal role in ensuring Benuvia's products meet the highest regulatory standards. With his expertise in FDA compliance and pharmaceutical manufacturing, he bridges the gap between innovation and QA, making us a trusted partner in delivering safe and effective therapies.

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SUMMARY

CBD products are widely available, but not all are created equal. Without strict regulatory oversight, many products lack consistency, safety, and effectiveness. Also, misleading claims in the CBD industry put consumers at risk and undermine trust. This whitepaper explores the importance of pharmaceutical-grade manufacturing in ensuring consumer safety and trust and sheds light on false marketing tactics and the steps consumers and businesses can take to ensure they are purchasing truly high-quality products.





Our History of Excellence. Benuvia has been at the forefront of cannabinoid manufacturing for over a decade, specializing in pharmaceutical-grade products. Our Dronabinol API is widely regarded as the best in the market, offering unmatched consistency, purity, and reliability. Through our state-of-the-art FDA-inspected and approved facility, Benuvia has consistently pushed the boundaries of innovation while maintaining an unwavering commitment to compliance and quality. Whether it's pioneering new methods for cannabinoid production or supporting the development of life-changing therapies, we bring unparalleled knowledge and experience to every project.

FDA APPROVALS: NUTRACEUTICAL AND FOOD FACILITIES VS. PHARMACEUTICAL MANUFACTURING FACILITIES

Understanding the difference in regulatory standards between nutraceutical and food facilities and pharmaceutical manufacturing facilities is critical for ensuring safety, quality, and reliability in the products consumers and businesses choose.

Regulatory Oversight:

- *Nutraceutical and Food Facilities:* These facilities are subject to basic FDA regulations under the Food Safety Modernization Act (FSMA). While they must comply with Good Manufacturing Practices (GMP) for food, the standards are less stringent and focus primarily on preventing contamination rather than ensuring therapeutic consistency.
- *Pharmaceutical Manufacturing Facilities:* Pharmaceutical facilities must comply with FDA-enforced Current Good Manufacturing Practices (cGMP). These standards require detailed documentation, periodic inspections, and validation of all manufacturing and testing processes to ensure products meet precise specifications for potency, purity, and safety.

Testing Standards:

- *Nutraceutical and Food Products:* Testing may be performed at third-party labs that are often not held to the same regulatory requirements as pharmaceutical labs. A study published in *Frontiers in Pharmacology* found inconsistencies in CBD product labeling, with potency deviations exceeding 10% in most samples ([Frontiers in Pharmacology](#)).
- *Pharmaceutical Products:* Testing in pharmaceutical facilities is conducted using validated methods under strict FDA oversight. This ensures that every batch of a drug product meets the defined standards for safety, efficacy, and consistency.

Traceability and Documentation:

- *Nutraceutical and Food Products:* Documentation requirements are minimal, with limited emphasis on batch traceability. This can make it difficult to identify and address issues in the supply chain. [The FDA's White Paper on Pharmaceutical Quality Oversight](#) discusses the deficiencies in record-keeping practices among non-pharmaceutical manufacturers.





- *Pharmaceutical Products:* Pharmaceutical facilities maintain detailed records for every stage of production, ensuring complete traceability from raw material sourcing to final product release. This provides a robust mechanism for addressing potential issues quickly and effectively.

Focus on Consumer Safety and Efficacy:

- *Nutraceutical and Food Products:* These products are not required to demonstrate efficacy or undergo the same rigorous safety evaluations as pharmaceuticals. As a result, consumers face greater uncertainty regarding product performance and potential risks. This [NORML Analysis](#) highlights how mislabeled and unregulated CBD products often contain harmful contaminants.
- *Pharmaceutical Products:* Products are subjected to extensive clinical testing and post-market surveillance to ensure their safety and efficacy. A Frontiers in Pharmacology study examining mislabeled CBD products found significant inconsistencies in cannabinoid content and contamination risks. The study concluded, “These findings highlight the need for proper regulatory oversight of cannabinoid-containing products to ensure quality assurance and deter misleading or unfounded health claims in product marketing” ([NORML Report](#)). Unlike nutraceuticals, pharmaceutical products are regulated through strict FDA oversight, ensuring proper labeling, validated efficacy, and comprehensive quality control measures to safeguard consumer health.

KEY COMPARISON TABLE

ATTRIBUTE	NUTRACEUTICAL & FOOD FACILITIES	PHARMACEUTICAL MANUFACTURING FACILITIES
REGULATORY STANDARDS:	FSMA, Food GMP	cGMP (Current Good Manufacturing Practices)
TESTING REQUIREMENTS:	Unvalidated, less stringent	Validated, FDA-inspected
DOCUMENTATION:	Minimal	Comprehensive traceability
CONSUMER SAFETY FOCUS:	Preventing contamination	Ensuring safety, efficacy, and consistency
EFFICACY DEMONSTRATION	Not required	Required through clinical testing







Nutraceutical & Food **VS** Pharmaceutical

The key differences in regulatory standards.

Regulated under the Food Safety Modernization Act (FSMA)	X	Regulated under Current Good Manufacturing Practices (cGMP) by the FDA
Follows Good Manufacturing Practices (GMP) for food, but with less stringent oversight	X	Strict documentation & batch traceability are required for every step of production
No requirement for clinical trials to prove efficacy	X	Clinical trials & regulatory approvals required to prove safety and efficacy
Testing is optional and may not be validated or standardized	X	Validated testing methods are mandatory for all raw materials, intermediates, and final products
COAs may lack transparency and use unvalidated testing methods	X	Routine FDA inspections ensure continuous compliance with manufacturing standard
Label claims are not strictly regulated, leading to potential misrepresentation	X	COAs must meet strict validation criteria, ensuring product consistency and accuracy
Limited documentation requirements, making product traceability difficult	X	Label claims must be backed by scientific data, preventing misleading marketing
Manufacturing facilities are inspected less frequently, often on a reactive basis	X	Risk management & quality assurance processes in place to protect consumer safety

Pharmaceutical manufacturing facilities operate under significantly higher standards than nutraceutical and food facilities. This difference translates directly into greater safety, quality, and reliability for pharmaceutical products. By choosing products manufactured in FDA-approved pharmaceutical facilities like Benuvia, consumers and businesses can ensure the highest levels of compliance and trust.





THE ILLUSION OF SAFETY: CERTIFICATES OF ANALYSIS (COAs)

For many, receiving a COA with their CBD purchase provides a sense of assurance that the product is safe and effective. While COAs are an important tool for verifying certain attributes of a product, they often have significant limitations:

Lack of Standardization. COAs from third-party labs may not adhere to validated testing methods, leading to inconsistent or inaccurate results. A study conducted in a Forbes report found that 25% of CBD products were not tested for purity, leaving consumers vulnerable to unsafe contaminants ([Forbes Report](#)).

Undetected Impurities. Without rigorous testing standards, COAs may fail to identify harmful contaminants such as heavy metals, pesticides, residual solvents, or microbial impurities.

Questionable Lab Practices. Many testing labs, though accredited, may not be held to regulatory standards required for pharmaceutical testing, resulting in unreliable data.

The truth is that a COA is only as reliable as the lab and methods used to generate it. For products manufactured without strict regulatory oversight, the risks of contamination, mislabeling, and inefficacy are significantly higher.

EMPOWERING CONSUMERS AND CUSTOMERS: HOW TO EVALUATE A COA

To take control of their safety and ensure they are purchasing reliable products, both consumers and companies should evaluate COAs carefully. Here are key steps to determine if a COA is trustworthy:

1. Check the Lab Accreditation. Look for COAs from labs accredited by reputable organizations like ISO/IEC 17025. Accreditation indicates the lab follows internationally recognized standards.

2. Verify Testing Methods. Ensure the COA specifies the use of validated methods for testing potency, purity, and contaminants. Reliable testing methods are critical for accurate results.

3. Examine Batch-Specific Data. The COA should include detailed information specific to the batch being purchased, such as:

- Lot number
- GMP Batch Manufacturing date
- Expiration date

4. Look for Comprehensive Testing.

- A reliable COA will test for and report on:
- Potency (e.g., CBD concentration)
- Contaminants (e.g., heavy metals, pesticides, residual solvents, microbial impurities)
- Stability and shelf life





5. Traceability. Confirm that the COA is directly tied to the product and manufacturer. Transparency in sourcing and testing builds trust.

6. Regulatory Compliance. Ensure the manufacturer operates in compliance with regulatory standards like GMP. Products made in FDA-inspected facilities are more likely to meet stringent quality requirements.

By following these steps, both consumers and prospective customers can identify trustworthy COAs and make informed decisions about the products they use or distribute.

UNDERSTANDING THE RISKS OF NON-PHARMACEUTICAL-GRADE PRODUCTS

Hemp-derived CBD products marketed as nutraceuticals or consumables are not regulated to the same degree as pharmaceutical-grade APIs and drug products. This disparity can pose serious risks, including:

Inconsistent Quality. Products may vary in potency and purity, leading to inconsistent results and potential over- or under-dosing.

Contaminants. Without rigorous testing and oversight, products may contain harmful impurities such as:

- Heavy metals (e.g., lead, arsenic)
- Pesticides and herbicides
- Microbial contaminants (e.g., mold, bacteria)
- Residual solvents used during extraction

Unverified Efficacy. Nutraceutical products do not require evidence of therapeutic effectiveness, leaving consumers and businesses without assurance that the product will deliver the intended benefits.

THE MISLEADING CLAIMS OF “API CERTIFICATION”

Some companies market their products as “API certified,” but it is crucial to understand what this claim actually means—and what it doesn’t. “API certification” is typically a *paid-for designation* that:

Lacks Regulatory Oversight. These certifications do not involve ongoing inspections or audits by regulatory authorities such as the FDA.

Fails to Validate Testing Methods. Certification often does not extend to third-party labs, many of which use unvalidated methods, leading to inaccurate results.

Provides No Legal or Safety Guarantees. Unlike FDA approvals, these certifications do not ensure compliance with pharmaceutical-grade manufacturing standards.

Both consumers and businesses should approach such claims with caution and prioritize products manufactured under regulatory frameworks designed to protect public health.





BENUVIA'S COMMITMENT TO PHARMACEUTICAL-GRADE PRODUCTS

At Benuvia, we are committed to providing both consumers and our partners with products that meet the highest standards of safety, quality, and efficacy. As a pharmaceutical API and drug product manufacturer, we operate under the most stringent regulatory standards in the industry:

FDA-Approved Facility:

- Benuvia operates an FDA-approved facility that is regularly inspected to ensure compliance with Good Manufacturing Practices (GMP).
- Our facility is also inspected by international regulatory bodies, ensuring adherence to global quality standards.

Validated Testing Methods:

- All our APIs undergo rigorous testing using validated methods to ensure accuracy, consistency, and reliability.
- Testing includes evaluations for potency, purity, and the absence of harmful contaminants such as heavy metals, pesticides, and residual solvents.

Drug Master Files (DMFs):

- Our APIs are supported by active Drug Master Files (DMFs), which provide detailed documentation of manufacturing processes, quality control measures, and compliance with regulatory requirements.

Pharmaceutical-Grade Standards:

- Unlike nutraceutical-grade products, our APIs are manufactured to meet the stringent requirements of pharmacopeial standards (e.g., USP, EP).
- Every batch is accompanied by a comprehensive Certificate of Analysis (COA) that reflects the highest level of regulatory compliance.

End-to-End Traceability:

- From raw material sourcing to final product release, our processes are designed to ensure complete traceability and accountability at every step.

WHY REGULATORY OVERSIGHT MATTERS

Choosing a product manufactured under strict regulatory oversight provides several key advantages:

Safety: Products are free from harmful contaminants, providing peace of mind.

Effectiveness: Pharmaceutical-grade APIs are backed by evidence of consistent therapeutic performance.

Reliability: Strict manufacturing controls ensure consistent quality from batch to batch.

When consumers and businesses choose products made with Benuvia's APIs, they can trust that they meet the highest standards of safety, quality, and efficacy.





CONCLUSION: MAKING INFORMED CHOICES

In an industry where not all products are created equal, it is vital for both consumers and businesses to look beyond marketing claims and evaluate the true safety and quality of the products they use or distribute. Certificates of Analysis and “API certification” can be misleading without the backing of rigorous regulatory oversight.

By following the steps to evaluate COAs and choosing products made with pharmaceutical-grade APIs, consumers and partners can take control of their safety and ensure reliability every time.

At Benuvia, we are proud to set the benchmark for pharmaceutical-grade quality. By choosing products made with our APIs, you can be confident you are making the safest, most informed choice for your health or business. For more information about Benuvia’s pharmaceutical-grade CBD APIs and our commitment to quality, visit www.benuvia.com.

A MESSAGE FROM THE AUTHOR

My passion lies in ensuring consumers have access to safe, reliable, and effective products. Confusion and misinformation exists in the CBD space because many manufacturers make claims that simply don’t hold up to scrutiny. This not only puts consumers at risk but also undermines trust in an industry that has so much potential to help people.

Benuvia is dedicated to raising the standard for cannabinoid-based products through pharmaceutical-grade manufacturing practices and rigorous regulatory compliance. By empowering consumers with the knowledge to make informed decisions and helping our partners understand the importance of quality and oversight, we can build a future where safety and trust are the cornerstones of every CBD product.

I am deeply committed to ensuring the products we deliver are effective and held to the highest standards of safety and quality. I hope sharing this white paper sheds light on the risks of unregulated products and emphasizes the importance of choosing pharmaceutical-grade solutions. Together, we can create an industry where consumers trust what they buy and feel confident in the choices they make.

Disclaimer: This white paper is for informational purposes only and is not intended as medical advice. Always consult with a qualified healthcare professional before using any CBD or hemp-derived products.

ABOUT BENUVIA

Benuvia Operations, LLC is a global Contract Development and Manufacturing Organization (CDMO) that helps pharmaceutical, and biotech companies deliver life-changing therapies to patients in need. The company provides end-to-end development and manufacturing services for

Active Pharmaceutical Ingredients (APIs) and finished dosage products and has extensive experience with cannabinoids, psychedelics, and other controlled substances. Benuvia operates an 83,000 square foot, best-in-class manufacturing facility in Round Rock, Texas that can produce Schedule

I-V compounds, offering comprehensive solutions for companies throughout the entire drug development lifecycle—from API Process Development, clinical trial supply to commercial production.

Visit us at www.benuvia.com

