Greenleaf Health

CANNABIS-DERIVED PRODUCT SERVICES

The Agriculture Improvement Act of 2018 (2018 Farm Bill) removed hemp – defined as cannabis (Cannabis sativa L.) and derivatives of cannabis with no more than 0.3% THC on a dry-weight basis – from the definition of marijuana in the Controlled Substances Act (CSA). Since then, the market has been flooded with products containing cannabidiol (CBD) and other cannabis-derived substances. Yet, while passage of the 2018 Farm Bill changed the legal status of cannabis under the CSA, it did not alter the authority of the U.S. Food and Drug Administration (FDA) to regulate products containing these substances.

As a result, the expanding cannabis industry is plagued by regulatory uncertainty, and the CBD market is thriving amid intermittent and targeted enforcement. Industry awaits highly anticipated Congressional action which will clarify the future regulatory status of these products.

In the interim, companies developing cannabis-derived products require a trusted partner to help them analyze risk and strategically enter the booming market. With decades of FDA, legal, and policy experience, Greenleaf's team of respected professionals brings unmatched expertise that companies need when working directly with the FDA and when navigating today's evolving regulatory environment.

STRATEGIC & TECHNICAL CAPABILITIES

Greenleaf offers expert regulatory consultation on all aspects of the FDA's regulation of cannabis-derived products, including dietary supplements, cosmetics, foods, and other consumer products.

Greenleaf specialists provide strategic and technical guidance on cannabis-derived product development, marketing, manufacturing, and compliance, with expertise in:

- Regulatory risk assessment
- Clarification of regulatory pathways and requirements
- Product labeling and promotion
- Product quality, manufacturing, and compliance
- Compliance assessments, remediation, and inspection readiness
- Regulatory policy consultation, strategic planning, and communications

ABOUT GREENLEAF

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

COMPREHENSIVE SERVICES

Greenleaf's robust blend of technical skill and FDA institutional knowledge enables the firm's team to provide unmatched guidance to companies developing medical products for the U.S. market.

This wealth of experience allows the Greenleaf team to work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges.

Greenleaf is a regulatory consulting firm and does not provide legal advice or legal services.

www.greenleafhealth.com

FULL-SERVICE SUPPORT

Regulatory Analysis

Greenleaf works with clients to clarify the regulatory requirements for products containing CBD and other cannabinoids, including dietary supplements, cosmetics, and other consumer products. Our capabilities include:

Product risk assessment to determine the likelihood of FDA enforcement

Analysis of labeling claims to ensure that statements adequately represent the product and are in compliance with the Federal Food, Drug, and Cosmetic Act

Clarification of regulatory pathways and required premarket submissions for FDA-regulated products

Guidance on state regulation and its role within the broader regulatory framework

Product Quality & Compliance

Greenleaf's Product Quality, Manufacturing, and Compliance Team, along with its network of independent compliance experts, offers credible, informed quality, manufacturing, and compliance guidance, including:

Identification, analysis, and discussion of FDA enforcement trends in the cannabis-derived products space

Consultation on compliance with FDA manufacturing and quality controls, including current GXP regulations

Compliance assessments and gap analyses at both the facility and corporate levels for manufacturing and quality practices and systems

Inspection readiness services

Evaluation of and response to FDA regulatory correspondence and enforcement actions

FDA Communications & Interactions

Greenleaf's best-in-class experts bring value to any communication with the FDA. Strategic communication services include:

Recommending best practices for interaction and communication with the FDA

Providing guidance on FDA meeting requests and briefing packages and helping clients prepare for meetings with FDA staff

Reviewing all forms of written correspondence to facilitate effective interaction with the Agency

EXPERT TEAM

Greenleaf's decades of hands-on experience in the regulatory space is unmatched. The combined achievements and substantial qualifications of the Greenleaf team enable us to deliver best-in-class insight to clients developing and manufacturing cannabis-derived products.

LIZ OESTREICH

Senior VP, Regulatory Compliance

Diverse background and knowledge of legal, public policy, and non-profit sectors.

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

25-year compliance career, including serving as director of the FDA's drug compliance office.

TOM BERRY

Senior VP, Regulatory Compliance

20 years with the FDA and 10 years as a clinical/ hospital pharmacist.

MADELEINE GIAQUINTO

Director, Regulatory Affairs

Robust portfolio of regulatory compliance and federal health care advocacy experience.

COMPREHENSIVE SERVICES

Members of the Greenleaf team work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter complex regulatory challenges. Greenleaf's collaborative services include:

PRODUCT QUALITY

Greenleaf's Compliance Team provides services that are recognized as best in class by companies seeking to strengthen their quality management systems. Experts specialize in corporate quality and compliance systems; FDA inspections, communication, and enforcement processes; and the complete spectrum of compliance- and enforcement-related actions.

DRUGS & BIOLOGICAL PRODUCTS

Greenleaf experts specialize in providing strategic and technical guidance on medical product development, regulatory review, and postmarket requirements. The team's approach, firmly grounded in established principles of public health, is guided by decades of regulatory experience in drug and biological product development, spanning all therapeutic areas.

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