Greenleaf Health

COSMETICS REGULATORY SERVICES

Since enactment of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938, the evolution of cosmetic products on the U.S. market has presented the Food and Drug Administration (FDA) with unique regulatory challenges. These challenges, coupled with limited enforcement authorities, necessitated a broader, modernized regulatory framework for cosmetics.

Congress passed the Modernization of Cosmetics Regulation Act (MoCRA) in December 2022, to shift the FDA's cosmetics oversight further towards safety and quality in the cosmetics space. As a result, new regulatory requirements and FDA guidance for cosmetics manufacturers are forthcoming, giving companies and stakeholders a meaningful opportunity over the next several years to provide input.

Greenleaf Health serves as a trusted partner to both large and small clients developing and commercializing cosmetics as they navigate the complex landscape of FDA regulations and policies.

OUR COSMETICS SERVICES

Greenleaf provides guidance to cosmetics and aesthetic product manufacturers, beauty and personal care product companies, trade associations, and other stakeholders implementing and complying with FDA regulations and policies under the FD&C Act, including new MoCRA requirements, the Federal Fair Packaging and Labeling Act, and related statutes and regulations.

Greenleaf's cosmetic clients vary greatly in nature, scope, and levels of experience with FDA regulation. Our wide-ranging expertise enables us to advise companies:

- Entering the cosmetics space with limited FDA regulatory experience and/or knowledge
- With existing products in the cosmetics space that now need to interpret and comply with new FDA regulatory requirements under MoCRA
- Marketing cannabis-derived consumer products (e.g., CBD-containing products) in the cosmetics space
- Marketing novel products, such as innovative products or combination products that include a cosmetic with an over-the-counter drug or device, that are seeking assistance in complying with the most appropriate regulatory framework

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.

REGULATORY STRATEGY & COMPLIANCE

Greenleaf works with clients to clarify and support compliance with the regulatory requirements for consumer products marketed in the cosmetics space by:

- Providing guidance on FDA regulatory policies, programs, and procedures, including advising on the anticipated FDA jurisdictional determination for the product
- Advising on all aspects of MoCRA, including:
    - o New marketing, facility registration, and product listing requirements
    - o Small business accommodations under MoCRA
    - o FDA's expanded enforcement authorities under MoCRA, and relevant FDA enforcement trends
- Providing compliance services, such as:
    - o Helping clients understand applicable FDA manufacturing and quality controls, including GXP regulations for cosmetics
    - o Conducting compliance assessments and gap analyses of manufacturing and quality practices and systems, and providing inspection readiness services
    - o Assistance evaluating and responding to FDA communications related to enforcement actions and other regulatory correspondence
- Advising on FDA labeling requirements and product claims made on packaging and marketing materials
- Counseling on postmarket safety and reporting requirements

REGULATORY POLICY

Greenleaf helps clients keep pace with, and better navigate, the emerging regulatory landscape by:

- Advising clients on new FDA rules and reports mandated by MoCRA and their underlying impact on the broader regulatory framework
- Providing regulatory intelligence gathering and supporting clients in developing and implementing regulatory policy capabilities and strategies to effectively advance their priorities
- Identifying opportunities for clients to engage with the FDA and other stakeholders and leverage alliances to influence regulatory policy

EXPERT TEAM

JOHN TAYLOR

President and Principal, Compliance & Regulatory Affairs

Former FDA senior official held many high-profile positions at the Agency, as well as senior leadership roles within industry

CYNTHIA SCHNEDAR

Principal, Regulatory Compliance

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

KALAH AUCHINCLOSS

Executive Vice President, Regulatory Compliance

15 years of experience on Capitol Hill, in the private sector, and at the FDA, including role as Deputy Chief of Staff

MAURA NORDEN

Executive Vice President, Medical Device & Combination Products and General Counsel

15 years of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters

LIZ OESTREICH

Senior Vice President, Regulatory Compliance

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

SAMANTHA EAKES

Vice President, Regulatory Affairs

Master's in Public Health from the Boston University School of Public Health provides critical public health, advocacy, and regulatory knowledge

MADELEINE GIAQUINTO

Director, Regulatory Affairs

Robust portfolio of regulatory compliance and federal health care advocacy experience