



What the Modernization of Cosmetics Regulation Act Means for Hemp and CBD Cosmetic Manufacturers

MoCRA expands FDA’s authority over cosmetics and includes new requirements, such as safety substantiation, adverse event reporting, facility registration, product listing, and mandatory recall authority.

**By Evelina J. Norwinski,
Elizabeth Trentacost,
and Ryan D. White**
Arnold & Porter

On Dec. 23, 2022, Congress passed sweeping measures intended to strengthen the Food and Drug Administration’s (FDA) regulation of cosmetics. The measures were signed into law by President Biden on Dec. 29, 2022.

Titled the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), the measures were included in Congress’s \$1.7 trillion year-end government spending bill and are the first major amendments to the Food, Drug and Cosmetic Act’s (FDCA) cosmetics provisions since they were enacted in 1938.¹

The law both expands FDA’s authority over cosmetics and includes new requirements for cosmetics, including safety substantiation, serious adverse event re-

porting, facility registration and product listing, and mandatory recall authority.

Hemp and cannabidiol (CBD) cosmetics already must comply with varied and, in some states, detailed state regulatory regimes. They will now need to prepare for an additional layer of federal regulation. Although neither existing FDA cosmetic regulations nor MoCRA include hemp or CBD-specific provisions, manufacturers and sellers of cosmetics and personal care products containing hemp and hemp ingredients (“hemp cosmetics”) will need to reconcile MoCRA requirements with the current array of state requirements.

The vast majority of MoCRA’s provisions become effective Dec. 29, 2023, giving companies time to comply, but some provisions have earlier or later effective dates. This article provides an overview of the current regulatory status for hemp cosmetics, the impact of Mo-

CRA, and key takeaways for companies considering the sale of hemp cosmetics as part of their product portfolio.

CURRENT REGULATORY STATUS OF HEMP COSMETICS

FDA's treatment of hemp or hemp-derived ingredients (including CBD) in cosmetic products aligns with its approach to cosmetic ingredients generally, and MoCRA does not inherently change the agency's posture. Hemp ingredients, like all other cosmetic ingredients not covered by a particular statute or regulation, must comply with applicable requirements.

For example, hemp or hemp-derived ingredients cannot be used if they adulterate or misbrand the product in any way. A cosmetic is adulterated if it bears or contains any "poisonous or deleterious substance that may render it injurious to users under the conditions of use prescribed in the labeling" or under common or usual conditions of use.² A cosmetic is misbranded if, for example, the label or labeling makes false or misleading claims,³ or claims to affect the structure or function of the body (i.e., "drug" claims).

Since the federal legalization of hemp in 2018 as part of the 2018 Farm Bill,⁴ states have stepped in to regulate hemp cultivation, processing, and sale. These regulatory regimes include regulation of products containing hemp and hemp-derived ingredients such as CBD.

As of this writing, approximately 15 states have laws and/or regulations specific to hemp cosmetics.⁵ These laws include requirements for licensing,⁶ pre-approval of products,⁷ THC content,⁸ testing,⁹ and packaging and labeling.¹⁰ Companies should expect to see additional states promulgating regulations over time.

CORE MOCRA REQUIREMENTS AFFECTING THE SALE OF HEMP-CONTAINING COSMETICS

MoCRA dramatically changes the regulatory landscape for cosmetic products, including a company's pre- and post-market compliance obligations, whether or not the products contain hemp or hemp-derived ingredients.

We summarize herein core requirements that may be of particular interest to companies engaged in the manufacture and sale of hemp-containing cosmetics, and flag intersections with existing state laws governing hemp cosmetics.

REGISTRATION & LISTING

Generally, firms that own or operate a facility that manufactures or processes cosmetics for distribution in the U.S. will be required to register their facility with FDA. This requirement will impose an additional registration requirement on facilities that already need to register a hemp or CBD processing facility under state law.¹¹

Existing facilities must register with the FDA by Dec. 29, 2023, while new facilities must register within 60 days of starting manufacturing or processing of cosmetics. Companies must submit product listings that include a list of ingredients in each product. New products must be listed with FDA within 120 days of marketing the product, while listings for existing products must be submitted by Dec. 29, 2023.

Limited exceptions to registration and listing requirements are available for small businesses (those with average gross annual sales from the previous three years of less than \$1 million).

Existing federal and state regulations governing hemp cosmetics require a list of ingredients on the label,¹² so manufacturers should already have collected this information.

SAFETY SUBSTANTIATION

Pre-MoCRA, cosmetic firms were restricted from introducing unsafe or adulterated products into the market, and were obligated to adequately substantiate safety for each ingredient used in the product prior to marketing. Each ingredient or product lacking substantiation would be misbranded unless labeled with "Warning – The safety of this product has not been determined."

MoCRA advances safety substantiation for cosmetic products and ingredients by requiring that firms both maintain records supporting that there is adequate substantiation of safety for their products and ingredients.

This means that firms must have "tests or studies, research, analyses, or other evidence or information that is considered—among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients—sufficient to support a reasonable certainty that a cosmetic product is safe."¹³

By "safe," the law requires the cosmetic product and any ingredient not be injurious to users under the conditions in the labeling or customary or usual use. FDA may consider the cumulative or other relevant exposure to the product and any ingredient therein when evaluating safety. Compliance is required by Dec. 29, 2023.

Firms marketing cosmetics containing hemp or hemp-derived ingredients will need to ensure they have adequate substantiation of safety for their products and hemp ingredients. In light of FDA's finding that the dietary supplement and foods pathway is not appropriate for CBD, it is reasonable to expect that FDA may look more carefully at firms' safety substantiation for cannabis-containing cosmetics.

Indeed, the safety of CBD in cosmetics is an area of interest for FDA that may evolve. At the 164th meeting of the Cosmetic Ingredient Review (CIR) Expert Panel (March 2023), FDA asked that the body prioritize the review of the safety of CBD in cosmetics. Back in 2020, FDA requested that CIR review CBD in cosmetics, but at the time, there were no for-