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Prostaglandin Analogues In Eyelash Cosmetics: Rodan & Fields To Settle Litigation For $38M

by Ryan Nelson

R&F will establish funds totaling $38m to put the kibosh on claims of fraud and unfair competition in US federal and state class actions, while maintaining it never intended its prostaglandin analogue-containing Lash Boost to impart drug-like structure and/or function effects on the human body. The settlement does not require R&F to stop selling Lash Boost or reformulate the product.

San Francisco-based Rodan & Fields, LLC will shell out $38m to settle multiple class actions in US and California state courts concerning the multi-level marketing firm's Lash Boost conditioning serum and the prostaglandin analogue that powers it.

According to court documents and the *settlement website*, California Superior Court Judge Ethan Schulman preliminarily approved plaintiffs' unopposed settlement motion on 8 March, setting a final approval hearing for 14 September.

Upon final approval, the settlement will resolve claims in Scherr, et al. v. Rodan & Fields, LLC and Gorzo, et al. v. Rodan & Fields, LLC, both filed in the state trial court, as well as allegations in a related case pending in the US District Court for the Northern District of California, Barbara Lewis, et al. v. Rodan & Fields, LLC. (Also see "*Rodan + Fields Prostaglandin Lash Boost Suit Appears Headed For Settlement*" - HBW Insight, 13 Jul, 2021.)

The US FDA has suggested in warning letters that just the use of

prostaglandin analogues in eyelash or brow products – combined with such claims as "enhance the appearance of your lashes and brows" and "fuller healthier-looking lashes" – could signal intended use that triggers new drug requirements.

In all three cases, plaintiffs allege that Lash Boost is an unapproved drug product with potential to harm consumers due to its use of isopropyl cloprostenate, a substance with hormonal effects belonging to a class of prostaglandin analogues that has been linked to serious adverse events.

Had such information been made known to them through product labeling or other disclosures, plaintiffs would not have purchased the product, they say.

A number of the plaintiffs allege they suffered not only economic but also bodily injuries from using Lash Boost, ranging from irritation, inflammation, blocked oil glands and bacterial infections to vision impairment and temporary changes in eye color.

They cite a litany of alleged violations including false advertising, fraud, negligent misrepresentation, and unfair competition under state, federal and common law.

"Defendant knows, or reasonably should know, that Lash Boost is a drug, that it is illegally sold without having gone through the proper regulatory approval processes, and that its ingredients are associated with serious adverse effects," the plaintiffs say.

"Accordingly, Defendant's labeling, advertising, and marketing of Lash Boost as 'not a drug product,' 'safe and non-irritating,' 'not contain[ing] any over-the-counter (OTC) or drug ingredients,' 'contain[ing] only cosmetic ingredients,' and 'not associated with any significant side effects,' as well as its material omissions signifying that Lash Boost is legally saleable, are deceptive," they say.

R&F denies that it has marketed Lash Boost for anything other than cosmetic uses, maintaining it has never intended Lash Boost to affect the structure and/or function of the human body, which would designate the product as an unapproved drug under the Federal Food, Drug and Cosmetic Act.

The settlement does not require R&F to stop selling Lash Boost or reformulate the product.

The lash serum currently sells for $155 at rodanandfields.com, touted as the "#1 Lash Serum in

the U.S. in 2020." According to the company, "Our famous lash conditioning serum is applied nightly to promote the appearance of longer, stronger and darker-looking lashes (or brows!)."

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In a 2011 warning letter to Lifetech Resources, LLC, marketer of the RapidLash and NeuLash brands, the FDA noted that prostaglandin analogues "are well known to have an effect on the structure or function of the body" and cited the company for "fail[ing] to reveal material facts with respect to consequences that may result from the use of the product." (Also see "*FDA's Warning To Lash-Growth Firm Shows Risks In Third-Party Claims*" - HBW Insight, 2 May, 2011.)

In a February opinion, the European Union's Scientific Committee on Consumer Safety characterized prostaglandin analogues as "widely known to be potent pharmacologically active substances" and expressed concerns about their safety in cosmetic products.

Stateside, one month later, the Cosmetic Ingredient Review's Expert Panel for Cosmetic Ingredient Safety decided not to prioritize prostaglandin analogues for evaluation in 2023, noting "these materials will have a biological effect." The panel has requested and will await input from the FDA before pursuing the question further. (Also see "*CIR Panel Throws Up Hands At Airbrush Ingredient Safety, Defers To FDA On Eyelash 'Enhancers'*" - HBW Insight, 21 Mar, 2022.)

Allergan PLC is FDA-approved to make eyelash-growth claims for its Rx Latisse treatment, which contains prostaglandin analogue bimatoprost at 0.03% for treatment of "inadequate" eyelashes. The Dublin, Ireland-based pharmaceutical company has a history of suing marketers of cosmetic eyelash-enhancement products that contain prostaglandin analogues for alleged patent infringement and unfair competition. (Also see "*Allergan Continues Legal Sparring With Cosmetic Eyelash-Growth Brands*" - HBW Insight, 20 Jun, 2011.)

R&F was founded in 2000 by Stanford-trained dermatologists Katie Rodan and Kathy Fields as an early entry in medical-cosmetic (dermocosmetic) skin care. The brand was snapped up by The Estee Lauder Companies, Inc. in 2003 and rolled out in department stores. (Also see "*Lauder Rodan & Fields Buy Adds Dermatological Brand To Skin Care Portfolio*" - HBW Insight, 21 Jul, 2003.)

In 2007, the founders repurchased the company and shifted to an MLM business model – aka, "Consumer Connected Commerce" – currently boasting more than 300,000 enrolled independent consultants, according to the company's website. Reportedly, the firm generated around $1.3bn

in revenues in 2019.

Plaintiffs say R&F should have trained its independent consultants to review and discuss product risks and benefits with customers to ensure that informed purchasing decisions could be made.

Under terms of the deal with plaintiffs, which R&F reached without admitting liability or wrongdoing, the firm will create cash and credit settlement funds – $30m and $8m, respectively – to compensate consumers nationwide who purchased Lash Boost between 1 October 2016 and 11 March 2022.

Authorized claimants will be eligible to receive up to $175 in cash or up to $250 in credit toward future R&F purchases. Repeat Lash Boost purchasers could receive greater cash or credit benefits if funds are not exhausted and they submit receipts or other accepted documentation.

Up to $16m of the funds will be used to cover settlement administration costs, payments to named class representatives for their service – $15,000 each – and plaintiffs' counsel's fees and expenses.