

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

January 25, 2018

The Honorable Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Commissioner Gottlieb:

I write to you today with grave concerns about certain cosmetic manufacturers' recent false and misleading marketing statements which erroneously suggest that the Food and Drug Administration (FDA) has found particular ingredients to be safe and effective. These statements risk deceiving consumers in a way that prevents them from making an informed choice about the products they use every day.

More specifically, it has come to my attention that Rodan + Fields, a cosmetics company that sells its products online and through multi-level marketing representatives, has been mischaracterizing FDA's position on the ingredient benzophenone. As you may know, benzophenone is chemical known to absorb ultraviolet rays. It is often used in personal care products as a sunscreen and may also be used to enhance fragrance.<sup>1,2</sup> California's Environmental Protection Agency and the World Health Organization International Agency for

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<sup>1</sup> Centers for Disease Control and Prevention (CDC), *National Biomonitoring Program, Benzophenone-3 (BP-3) Factsheet* (April 2017) ([https://www.cdc.gov/biomonitoring/Benzophenone-3\\_FactSheet.html](https://www.cdc.gov/biomonitoring/Benzophenone-3_FactSheet.html)).

<sup>2</sup> National Institutes of Health, U.S. National Library of Medicine, National Center for Biotechnology Information, *Compound Summary for CID 3102* (<https://pubchem.ncbi.nlm.nih.gov/compound/benzophenone#section=Top>).

Research on Cancer have identified this chemical as a possible carcinogen, and there is also evidence that benzophenone is an endocrine disrupter and may cause cancer.<sup>3,4</sup>

Rodan + Fields sells a number of products containing benzophenone, and is required under California's Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, to provide a warning regarding its use. Rodan + Fields' website offers the following warning:

For California customers:

*WARNING: This product can expose you to chemicals including Benzophenone, which is known to the State of California to cause cancer. For more information, visit the Proposition 65 website. Click here for more information about the FDA's position on Benzophenone.*<sup>5</sup>

The phrases "visit the Proposition 65 website" and "Click here" act as hyperlinks to external websites.

For some period of time prior to January 17, 2018, the "Click here" hyperlink directed consumers *not* to the FDA website or position on benzophenone, but rather to the website: <http://www.cosmeticsinfo.org>.<sup>6</sup> That website, which is maintained and paid for by the Personal Care Products Council (PCPC)<sup>7</sup>, summarizes findings by PCPC's Cosmetic Ingredient Review (CIR) Expert Panel concluding that benzophenone is safe for use in cosmetics and personal care products. It does not appear that FDA has made any public determination on the safety of benzophenone in personal care products, but the Centers for Disease Control and Prevention (CDC) has stated that "[t]he human health effects from skin exposure to low levels of BP-3 are unknown. ... More research is needed to assess the human health effects of exposure to BP-3."<sup>8</sup>

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<sup>3</sup> California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, *Benzophenone*, (June 2012) (<https://oehha.ca.gov/proposition-65/chemicals/benzophenone>).

<sup>4</sup> International Agency for Research on Cancer, *IARC Monographs 101, Benzophenone* (2013) (<https://monographs.iarc.fr/ENG/Monographs/vol101/mono101-007.pdf>).

<sup>5</sup> Rodan + Fields, *Reverse Brightening Regimen + Active Hydration Serum Special* (<https://www.rodanandfields.com/Shop/Product/RVRBH01#ingredients>)(accessed Jan. 9, 2018).

<sup>6</sup> Cosmetics Info, *Benzophenone-1, -3, -4, -5, -9 and -11* (<http://www.cosmeticsinfo.org/ingredient/benzophenone-1-3-4-5-9-and-11>).

<sup>7</sup> The Personal Care Products Council is a national trade association representing the global cosmetic and personal care product industry.

<sup>8</sup> Centers for Disease Control and Prevention (CDC), *National Biomonitoring Program, Benzophenone-3 (BP-3) Factsheet* (April 2017) ([https://www.cdc.gov/biomonitoring/Benzophenone-3\\_FactSheet.html](https://www.cdc.gov/biomonitoring/Benzophenone-3_FactSheet.html)).

Rodan + Fields' action at a minimum could mislead consumers and possibly place their health at risk. Their website erroneously states that it will provide further information from FDA, the agency charged with regulating cosmetics, but instead directed consumers to a website that is fully funded by the cosmetics industry itself and which outlines the industry's self-assessment on the safety and use of benzophenone. Consumers may thus be easily duped into believing that the website Rodan + Fields redirects to is an accurate or unbiased representation of FDA's position on this ingredient, and may have no idea that the website is actually funded by the cosmetics industry. This deceptive action on the part of Rodan + Fields is not consistent with the public health goal of helping consumers make informed decisions regarding product purchase or protecting consumers from potential health hazards.<sup>9</sup>

Given this, I urge FDA to investigate the actions of Rodan + Fields, and respectfully request you answer the following questions by February 16, 2018:

1. Is the agency aware of the misrepresentation of FDA's position on benzophenone by Rodan + Fields? If so, when did the agency become aware of this, and what actions, if any, has the agency taken to rectify this situation?
2. Rodan + Fields' Proposition 65 warnings appear on product pages beneath other information about the cosmetic products for sale. This other information includes product descriptions, directions for use, and ingredient lists. This may be the only information immediately available to the consumer at the time of online product purchase.
  - a. Does the information provided on the Rodan + Fields product pages constitute "labeling" under the Federal Food, Drug, and Cosmetic Act (FDCA) or the Fair Packaging and Labeling Act?
  - b. FDA has noted that labeling may be considered misleading "not only because a label statement is deceptive but also because a material fact is not revealed on a label."<sup>10</sup> If the information on Rodan + Fields online product pages is considered labeling, has the FDA reviewed this information to determine whether this labeling is false and misleading?
  - c. If this information is not considered labeling, or if this labeling is not misleading, what enforcement action can the agency take to address false and misleading claims by cosmetic manufacturers, such as Rodan + Fields?

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<sup>9</sup> While the hyperlinks on Rodan + Fields' website have since been updated to redirect to FDA's website, the link still does not guide consumers to any information outlining the agency's position on benzophenone.

<sup>10</sup> Food and Drug Administration, *Cosmetics, Cosmetic Labeling Guide* (<https://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126444.htm>).

The Honorable Scott Gottlieb, M.D.

January 25, 2018

Page 4

3. What information, if any, does FDA provide on the agency's website regarding benzophenone? Further, what information, if any, will FDA provide on the agency's website moving forward to correct any mischaracterizations made by Rodan + Fields?

I have long advocated for greater transparency in the cosmetic and personal care product industry, because consumers deserve to have access to full, accurate, and unbiased information regarding the products they are purchasing. I continue to work in Congress to pass legislation that would give FDA greater authority over cosmetics and personal care products because it is clear that some manufacturers may be marketing contaminated or harmful products and misleading consumers about the safety of their products. This incident serves as one more example of why FDA and Congress must come together to enact changes to our cosmetic regulatory framework to ensure that consumers are not harmed by the products they use every day.

If you have questions regarding this request, please have your staff contact Kimberlee Trzeciak or Christina Calce of the Democratic Committee staff at (202) 225-3641.

Sincerely,

A handwritten signature in blue ink that reads "Frank Pallone, Jr." with a stylized flourish at the end.

Frank Pallone, Jr.  
Ranking Member