

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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March 8, 2016

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

I write to you to express my concern over the ongoing safety issues related to the use of Guthy-Renker LLC's hair care product, WEN Cleansing Conditioner, and request that the Food and Drug Administration (FDA) provide further information about the steps the agency is taking to address these issues.

It has come to my attention that more than 17,000 consumers have filed complaints with Guthy-Renker as a result of hair loss associated with the use of WEN Cleansing Conditioner. Complaints filed by thousands of customers on product forums, retail web sites, and consumer sites detail a number of adverse events related to the use of the product, including significant hair loss, visible bald spots, hair breakage, scalp irritation, rash, and burning of the scalps and eyes, among other complaints. According to court documents, one consumer began losing "substantial and abnormal amounts of hair" within the first two weeks of using WEN Cleansing Conditioner.¹ Despite discontinuing use, hair loss continued for nearly three weeks, ultimately resulting in the loss of up to one third of the consumer's hair.² It is further concerning that consumer complaints related to hair loss or hair breakage associated with the use of WEN Cleansing Conditioners date as far back as late 2008.³

¹ First Amended Complaint, *Friedman v. Guthy-Renker LLC*, Case No. 2:14-cv-06009-ODW-AGR (C.D. Cal. Nov. 23, 2014).

² *Id.*

³ Minutes in Chambers granting in part and denying in part Plaintiff's Motion to Compel Further Responses to Document Requests, *Friedman v. Guthy-Renker LLC*, Case No. 2:14-cv-06009-ODW-AGR (C.D. Cal. Aug. 24, 2015).

Despite long-standing knowledge of safety issues related to the use of WEN products, and thousands of consumer complaints, Guthy-Renker continues to deny safety issues associated with use of WEN hair care products: "There is no scientific evidence to support any claim that our hair care products caused anyone to lose their hair. There are many reasons why individuals may lose their hair, all unrelated to WEN hair products."⁴

Given the increasing number of consumers experiencing adverse events related to the use of Guthy-Renker products, I respectfully request a response to the following questions no later than March 25, 2016:

1. When and how did FDA first become aware of safety issues associated with the use of WEN Cleansing Conditioners? Upon learning of these safety issues, what steps, if any, did the agency take to address these concerns? Further, please detail all communication between Guthy-Renker and FDA relating or referring to safety issues associated with the use of WEN hair care products.
2. What information, if any, has Guthy-Renker shared with the agency regarding the safety of its hair care products, including WEN Cleansing Conditioner? Has the agency reviewed the ingredients included in WEN Cleansing Conditioner to determine the cause behind the hair loss and hair breakage experienced by consumers?
3. Has FDA received access from Guthy-Renker to all assessments and records substantiating the safety of WEN hair care products and compliance with appropriate quality standards or Good Manufacturing Practices? If yes, when did the agency first access this information? If no, has the agency requested access to such information?
4. Has FDA conducted an inspection of the manufacturing facility that produces WEN Cleansing Conditioner to determine if the proper controls and practices are being followed? If yes, when did the agency conduct this inspection? If no, please explain why.
5. Has FDA received adverse event reports related to the use of WEN Cleansing Conditioner? If so, please provide additional information regarding these reports, including how many adverse event reports the agency has received thus far and the nature of the adverse events that have been reported.
6. Has FDA requested that Guthy-Renker, LLC and Chaz Dean, Inc. conduct a recall of WEN Cleansing Conditioner? If so, when does the agency anticipate this recall to be initiated by the companies? If not, please explain why.
7. Does FDA have sufficient authority currently to oversee this product? If so, please explain why. If no, please explain why.

⁴ *Popular Hair Product Line Wen Sued for Allegedly Making Women Go Bald*. NBC News (Dec 15, 2015) (online at <http://www.nbcnews.com/business/business-news/popular-hair-product-line-wen-sued-allegedly-making-women-go-n480276>).

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If you should have any further questions, please contact Kimberlee Trzeciak of my 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