



United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

May 8, 2017

Andrea C. Levine, Esq.
Senior Vice President, Director
National Advertising Division
112 Madison Avenue, 3rd Floor
New York, NY 10016

Re: Advertising Claims for Prestige Brands, Inc.'s Nix Ultra Lice Removal System

Dear Ms. Levine:

Last month, you referred to the FTC the NAD's compliance investigation of Prestige Brands, Inc.'s advertising claims that its Nix Ultra Lice Removal System "kills lice, eggs and super lice." Because Prestige Brands declined to comply with NAD's recommendations to discontinue these claims, you referred this matter to the FTC for our review.

Your referral indicated that after NAD completed its inquiry and closed its record, Prestige Brands submitted the Food and Drug Administration's response to its 510(k) premarket notification of intent to market this product (510(k) Number K163401). FDA's March 21, 2017 response states that FDA determined this product was substantially equivalent to legally marketed predicate devices for the following indications for use: "Nix® Ultra Lice Treatment Kit is intended to kill and remove head lice and their eggs from adults and children two years of age or older." FDA's 510(k) Summary acknowledges that Prestige Brands' product "has an additional action of killing lice and is intended for children 2 years and older," but states, "[t]hese minor differences between the subject and predicate do not raise different question of safety or effectiveness." https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163401.pdf

Upon review of this matter, we have determined not to take additional action at this time. In coming to this conclusion, we considered a number of factors related to resource allocation and enforcement priorities, as well as the nature of any FTC Act violation and the type and severity of any consumer injury. The FTC reserves the right to take such further action as the public interest may require.

Very truly yours,

Devin W. Domond
Chief of Staff for Advertising Practices