

**STATEMENT OF CHAIRWOMAN EDITH RAMIREZ AND
COMMISSIONER JULIE BRILL**

FTC v. Springtech 77376, LLC, et al., (Cedarcide Industries, Inc.)

July 16, 2013

We write to explain our support for the remedy imposed by the settlements in this matter which requires pre-approval from the Food and Drug Administration (“FDA”) as substantiation for future disease treatment and prevention claims. We approve of the settlements notwithstanding the Commission’s recent decision in *POM Wonderful, LLC* in which we declined to impose an FDA pre-approval requirement for the food products in question. In *POM*, we emphasized that our ruling there “does not foreclose that we may again conclude, in an appropriate case, that FDA pre-approval would be an appropriate remedy.”¹ We believe this is such a case.

The defendants here advertised their cedar oil product Best Yet! as a “natural,” “organic,” and “non-toxic” head lice treatment. The Commission alleged that the defendants’ claims that Best Yet! is effective in treating and preventing head lice were false and unsubstantiated. We also alleged defendants falsely claimed that Best Yet! was developed for the Army at the request of the U.S. Department of Agriculture.

The FDA considers head lice infestation, or “pediculosis,” to be a medical condition and has determined that the medical consequences of misusing head lice treatments are significant. For example, some head lice products are not safe for use in children under the age of two. Even for products considered safe, the FDA warns of serious side effects for such young children, such as coma, seizure, or death.² To address both efficacy and safety concerns, the FDA regulates all head lice treatments under a Final Monograph.³ For all such treatments not listed in the Final Monograph, the FDA requires companies to file new drug applications and demonstrate that such treatments are safe and effective by conducting clinical trials on their product.⁴ The FDA has not approved cedar oil, the active ingredient in defendants’ product, as a safe and effective treatment for head lice.⁵ Consequently, the defendants’ claimed “natural” product is an

