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 unapproved drug under the Food, Drug, and Cosmetic Act ("FDCA"). Because defendants marketed Best Yet! as a treatment for a medical condition, it is also a "drug" under Section 15 of the FTC Act.[6] Under these circumstances, requiring the defendants to have FDA pre-approval as substantiation for future claims is particularly appropriate as it harmonizes their obligations under the FDCA and the FTC Act.

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[1] *POM Wonderful*, No. 9344, 2013 WL 268926, at *56 n.37 (F.T.C. Jan. 10, 2013).

[2] *See* FDA, *Consumer Health Information*, *Treating Head Lice*, July 2009 at 2, *available at* http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173526.pdf.

[3] The Final Monograph was originally issued on December 14, 1993, and was later updated on December 31, 2003. *See* 21 C.F.R. Part 358 (2013).

[4] Defendants' claim that Best Yet! is intended for use in treating head lice makes it a drug under the Food Drug and Cosmetic Act. *See* 21 U.S.C. § 321(g)(1)(B). Because Best Yet! is not generally recognized as a safe and effective treatment for head lice, the FDA considers it to be a new drug. *See* 21 U.S.C. § 321(p). New drugs may not be introduced into interstate commerce without prior approval from the FDA. *See* 21 U.S.C. § 355(a).

[5] *See* 21 C.F.R. § 310.545 (2013).

[6] 15 U.S.C. § 55(c).

Moreover, requiring FDA pre-approval as substantiation is especially warranted where the consequences of a false claim are high. A false claim here would result in untreated head lice infestations and an increased risk that the infestations will spread. Although head lice infestations are not as serious as many other diseases, they cause considerable economic and consumer harm. An estimated 6 to 12 million head lice infestations occur each year in the United States among children 3 to 11 years of age.[7] Treatment costs are estimated to be $1 billion.[8] In contrast, the cost of complying with the FDA regulatory scheme is not prohibitive for companies seeking to market head lice treatments. In the last two years alone, at least two companies have received FDA approval for head lice treatment products.[9] Finally, as noted above, there are safety concerns associated with head lice treatments. Although the complaint does not include any allegations regarding safety, at least one lawsuit has been filed against one of the defendants alleging that a child received second-degree burns to her ears after using Best Yet! as a head lice treatment.[10]

To lawfully market their head lice product, the defendants must comply with the FDA regulatory scheme. The FTC's settlements requiring them to obtain FDA pre-approval impose no additional burden. In our view, the defendants should not be permitted to skirt a well-established regulatory scheme for demonstrating the efficacy and safety of head lice treatments, especially when they falsely claimed that their product had the imprimatur of the federal government. The FTC's settlements will help ensure that the defendants stay within the bounds of the law.

[7] *See* CDC, Parasites – Lice – Head Lice Frequently Asked Questions, http://www.cdc.gov/parasites/lice/head/gen_info/faqs html (last updated Nov. 2, 2010).
[8] Frankowski, BL et al., 126 *Pediatrics* 392, 392 (2010).
[9] *See* Melanie Haiken, *3 New Head Lice Drugs Could Change How Lice Are Treated*, Forbes, Nov. 28, 2012, *available at* http://www.forbes.com/sites/melaniehaiken/2012/11/28/finally-a-new-head-lice-treatment-that-really-works/.
[10] *Wammer v. Cedarcide Indus., Inc*., No. 12-2-33857-4 KNT (Super. Ct. King County, Wash., filed Oct. 17, 2012).