A open letter from our Medical Director, Dr. Shelly Friedman to friends, colleagues and clients

Addressing 510K FDA filings, Double Blind Medical studies results and misleading information being desiminated by a competitor
Dear Colleagues:

As Medical Director & Advisor to Capillus® for the past year and a half, I would like to introduce myself and provide you with an update on the status of the clinical trials for the Capillus®272. I have been an active member of the Hair Restoration Society for the past 22 years, as well as a Founding President of the American Board of Hair Restoration Surgery. I have been performing hair transplant surgeries for the past 28 years, and presently, selling 25 Capillus®272 caps monthly.

Capillus® has consulted with the foremost individuals in the fields of optical engineering, lasers, medical device manufacturing and regulatory affairs throughout the world. We have engaged a top optical engineer in Europe to ensure we have the most efficacious design. We have hired consultants with excellent track histories on conducting clinical trials for medical devices, as well as submissions for 510K clearances to the FDA. We have engaged reputable firms with long
histories in regulatory affairs to ensure that we succeed. We have implemented quality systems to strive for continuous improvement to our products as well as responding swiftly to communications from the FDA for corrective actions. We continue to gain the approval of many of our peers and tremendous acceptance by physicians and patients alike.

Our medical trials have now concluded, and we are in the process of preparing the report for submission very shortly to the FDA. The great news from the preliminary data collected from our double blind clinical studies is that the Capillus® lasers deliver results and that laser output levels are in full compliance with IEC 60825-1 which addresses the MPE (Maximum Permissible Exposure) for various lasers classes. The Capillus® 272 also conforms to the ANSI Standards Z136.1, Z136.3, Z136.4.

In response to rumors from competitors suggesting that the Capillus®272 laser output is outside the allowable range for a class 3R laser product, we requested a study of the output levels of our product in comparison to that of a competitor. A leading optical engineer in the field of lasers analyzed a Capillus® sample and a LaserCap® sample. As per the results displayed below, the output of the Capillus® unit, which incorporated the corrective actions communicated to the FDA in 2013, fell well within the FDA’s acceptable maximum for a class 3R laser of 5 mW. The LaserCap® sample demonstrated similar output levels. I believe it is important to note that the lack of a warning letter from the FDA to Transdermal Cap, Inc. does not validate the class of laser output of their device, or optical functionality, clinical efficacy, compliance to any recognized standards or prevent the product being designated as an adulterated product by the FDA. It is a matter of fact, that the FDA considers all lasers and LEDs products to be classified as MEDICAL DEVICES, when used to stimulate hair growth.

CONCLUSION

Though both devices are similar in their modulated (pulsing) laser output, they have marked differences in pulse frequency, pulse width, and duty cycle. This variation in engineering pathways indicates only that there is more than one method to achieve a functional design. If there is any conclusion to be derived from this point, it is NOT that one method is better than the other. It would be incorrect to draw this conclusion and it would be pure speculation and not based in fact.

Hopefully, this communication helps to address any questions or concerns that our competitors may have spurred.

Capillus® was incorporated in 2012. As part of its ongoing research and development program, has recently completed an Institutional Review Board approved, randomized, placebo controlled, double blind clinical trial with the Capillus® 272. This RCT follows Good Clinical Practice as established by the FDA under 21 CFR 56. Further, the study is registered at www.clinicaltrials.gov, as required by federal law. Capillus® is presently filing a 510(k) Premarket Notification for the Capillus®272 and fully expects to receive a clearance within 90 days after filing.

Transdermal Cap, Inc. (LaserCap®) was incorporated in 2006 and as of today, we are not aware of any attempt to conduct a clinical trial or file a 510K with the FDA.

The Capillus® company, our committed employees, staunch investors, and I personally back the Capillus® products. We have been steadfast in protecting both patients and physicians by ensuring we have a safe product for consumers. We are here to answer any question or concerns you may have.

You are welcome to drop in at our facilities in Coral Gables at any day, anytime; you would see firsthand how Capillus® operates on a typical day. I encourage you to do this; I assure you will be quite impressed.

Fraternally,

Shelly Friedman, D.O., FAOCD
Medical Director & Advisor
Capillus, LLC serves to provide useful insight and helpful information to the millions of men and women losing hair, and those who care about them. Drawing on the knowledge and experience of world renowned physicians and scholars, our goal is to bring those hair loss sufferers with the latest in the treatment of hair loss as well as information on invasive and non-invasive procedures. We connect patients to physicians in the industry for a variety of treatments including new hair restoration products and services, psychological and physiological resources for hair loss, as well as to provide information to all those in need of factual hair loss information.

We welcome feedback on how we can better serve you. Your comments and questions will help to guide the direction our company takes.

Thank you,
Carlos Piña

Company Information
Capillus, LLC is a limited liability corporation based out of Miami, Florida. The principals of Capillus, LLC have had many years of experience in the hair restoration industry.

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