FDA Grants Clearance for the HairMax Dual 12 Model for the Treatment of Female Pattern Hair Loss

Lexington International, LLC is pleased to announce that it has received FDA Marketing Clearance for the HairMax Dual 12 home-use laser phototherapy device for hereditary hair loss in females.

Boca Raton,FL (August 24, 2011) - Lexington Int'l is proud to announce that the FDA has granted Marketing Clearance for their new model of a home-use laser phototherapy device, the HairMax Dual 12. Based in part on submission of clinical results which demonstrated efficacy and safety, the FDA Granted Class II Marketing Clearance 510(k) #K111714 indicated for the 'Treatment of Hair Loss and Promotion of Hair Growth in Females.' This new model utilizes a dual wavelength approach which provides added benefit in the treatment of hair loss. The HairMax LaserComb® product line offers the only home use devices that are clinically proven and have been granted FDA 510(k) Marketing Clearance for the treatment of hair loss in men and women.

To view the official FDA documents for this study, please click the following link:

http://www.hairmax.com/mediakit/docs/FDA_clearance_female_HM12Beam_COVER.pdf.

The HairMax clinical studies were conducted at three of the top dermatology research centers in the United States. The investigators were Wilma Bergfeld, MD – Cleveland Clinic, Maria Hordinsky, MD – University of Minnesota, and Lawrence Schachner, MD- University of Miami. The double blind study compared the HairMax Dual 12 to a control device and measured the change in terminal hair counts over a 26 week period. The study was conducted under an IRB (Investigational Review Board) protocol. monitored by a CRO (Contract Research Organization), and followed the FDA's Good Clinical Practice guidelines and was registered at:

http://www.clinicaltrials.gov/ct2/show/NCT01042756?term=HairMax+LaserComb&rank=6

The results of the clinical study showed that 94.8% of the subjects on the HairMax LaserComb Dual 12 experienced hair growth after 26 weeks of treatment. The results also showed a trend of continuous improvement during the trial and it is expected that this trend would continue with further treatment.

Furthermore, over the 6 month length of the trial, females using the HairMax LaserComb Dual 12 grew an average of 20.6 hairs per square centimeter, which is considered medically and scientifically significant, and the highest hair count recorded in the study was 68 hairs per cm2. In addition, a majority of the subjects on the HairMax also reported improvement in thickness and fullness of their hair and there were no reports of adverse side effects occurring during the trial. The results of this clinical trial closely matched the efficacy results seen in three recent clinical trials conducted with the HairMax. These results further validate that treatments with the HairMax LaserComb are consistently reproducible. In all of the clinical studies of females and males, significant results can be seen in as little as 16 weeks. The HairMax devices allow people to treat their condition in the privacy and convenience of their home. The HairMax is easy to use, requiring only one 10-15 minute session a day, 3 times a week.

Since 2001, Lexington has completed a total of seven clinical studies with 460 subjects and all of the studies have demonstrated the efficacy and safety of the HairMax LaserComb. These statistically significant clinical study results confirm the fact that the HairMax should be considered as a 'first line' treatment for appropriate people suffering from hereditary hair loss. The HairMax LaserComb devices feature a sleek, modern design and are now battery powered.

Mr. David Michaels, Managing Director said, "We are excited that this latest clinical study has once again validated the efficacy and safety of the HairMax in treating hereditary hair loss in men and women. Based on clinical results, consumer compliance, safety profile, and user satisfaction, we are emphatic in our belief that the HairMax LaserComb is the most efficacious out of all the other products approved by the FDA. Mr. Michaels further stated, "For over 23 years, there have been limited modalities for treating female pattern hair loss and the market is eager for a highly efficacious and user friendly product. With the FDA Clearance for the HairMax Dual 12, women now have an appealing and efficacious option to treat their hair."

Randy Veliky, the COO of Lexington International also commented that, "The results of the clinical studies demonstrated significant new hair growth. In review of the macro images, there was an evident increase in the number of hairs per follicular unit, conversion of vellus to terminal hairs, and revival of dormant hair follicles." Mr. Veliky further stated, "Lexington has a very active clinical agenda moving forward that will include investigation into LLLT mechanisms of action, the role of inflammation in hair loss and other possible treatment indications."

About Lexington International, LLC

Based in Boca Raton, Lexington International is a manufacturer and developer of advanced medical laser devices to treat hair loss and scalp disorders. Lexington International markets the only laser phototherapy device cleared for marketing by the FDA to promote hair growth in men suffering from certain classes of Androgenetic Alopecia. The company was one of just 14 leading manufacturing exporting companies nationwide to receive the 2009 U.S. President's "E" Award, which recognizes successes in world markets and subsequent contributions to the U.S. economy. Over the past 10 years and in over 155 countries worldwide, Lexington Int., LLC has helped hundreds of thousands of individuals improve their appearance with innovative products to treat their hair. **(www.hairmax.com)**

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