New FDA Clearance for the HairMax LaserComb Fills an Unmet Need of Providing an Effective, Non-drug Home-use Device For Treating Hair Loss.

Boca Raton, FL. (Oct 19, 2011) - Lexington International, LLC, is pleased to announce that the company has received FDA 510(k) #K112524 Marketing Clearance for two new models of the HairMax LaserComb®, laser phototherapy medical device for the treatment of hereditary hair loss in women.

FDA Clearance Letter Link:
http://hairmax.com/mediakit/docs/FDA_Clearance_adv7_pro12.pdf

Hereditary hair loss is a devastating condition affecting over 30 million women in the United States. Until recently, when the HairMax Lux 9 was initially FDA Cleared for marketing for treatment of females, there had been only one FDA approved drug for treating this condition in women. This latest FDA Clearance now expands the HairMax treatment options for the three of the HairMax LaserComb models, as an effective first-line treatment of hereditary hair loss in both men and women. This is the fourth FDA 510(k) Clearance for marketing granted to Lexington Int'l this year.

The HairMax LaserComb cordless models that are now available are the HairMax Advanced 7, the HairMax Lux 9, and the HairMax Professional 12. These devices are offered at varying price points which fit the needs of all people wishing to treat their hair loss condition. The HairMax is easy and convenient to use with treatments at home of just 9-15 minutes per day, three times per week to achieve results, which can be seen in as little as 12 weeks. Also, the HairMax is safe to use, as no serious side effects have ever been reported from use of the HairMax.

This FDA marketing Clearance for females combined with prior FDA marketing Clearance for males, provides the following official indication for the HairMax LaserComb.

The HairMax Advanced 7, Lux9, and the Professional 12 models are indicated to treat Androgenetic Alopecia, and promote hair growth in males who have Norwood Hamilton Classifications of IIa to V and in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and who both have Fitzpatrick Skin Types I to IV.

This latest milestone is the culmination of Lexington's goal to offer a complete line of innovative, cutting edge, phototherapy devices for treating hereditary hair loss in men and women around the world. These testimonials from satisfied users of the HairMax are typical of the numerous comments we have received: "It got to the point that I wasn't going out much anymore. I noticed that when I spoke to my relatives and friends they weren't looking directly at me – they were looking at my hairline and that made me feel even more self-conscious about my hair loss." And, "HairMax has rejuvenated my hair growth, my self-esteem and my confidence".

Link to Other testimonials: http://www.hairmax.com/lasercomb-reviews-testimonials

In four double-blind clinical studies on the treatment of androgenetic alopecia (hereditary hair loss) in both men and women over 93% of subjects in the HairMax LaserComb groups experienced hair growth at 6 months. These results were consistent in all studies showing that the results with the HairMax are reproducible and predictable. Since 2001, Lexington has completed a total of seven clinical studies with 460 subjects. All of the studies (including these four), have conclusively proven that the HairMax LaserComb family of products are efficacious and safe as first line therapy for appropriate classes of hereditary hair loss.

Mr. David Michaels, Managing Director of Lexington said, "We have spent 11 years of R&D, innovation, and the completion of seven clinical studies to bring these innovative products to market. This recent FDA marketing Clearance brings to fruition our goal of offering a complete line of laser phototherapy products for people who are suffering from hereditary hair loss. Our challenge now is not how to get there, but how to assure that we get this information about the HairMax out to the millions of people suffering from this devastating condition".

Randy Veliky, Lexington COO said: "This recent FDA Clearance means that the HairMax LaserComb with its patented technology and state of the art design, now solidifies the position of Lexington as the world-wide leader in the treatment of hair loss. No other company marketing a device of its kind for hair loss matches the breadth, scope, and depth of our product line."

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 Int'l markets the only laser phototherapy device with published clinical trial results proving efficacy and safety in a peer review journal. The company received the 2009 U.S. President's "E" Award, recognizing successes in world markets. The Medical Advisory Board of the company is comprised of world-wide authorities in the treatment of hair loss and scalp disorders. Over the past 11 years and in over 155 countries worldwide, Lexington has helped hundreds of thousands of individuals treat their hair condition and enrich their lives. **(www.hairmax.com)**

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Lexington International, LLC | 777 Yamato Road, Suite 105, Boca Raton, FL 33431 | 561.417.0200
www.HairMax.com