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LEXINGTON INTERNATIONAL, LLC  
PRESS RELEASE



## FDA Clears HairMax to Treat Female Pattern Hair Loss and Promote Hair Growth

Boca Raton, FL (June 6, 2011) - For the first time in twenty three years, a new home-use treatment for female hair loss is available. Lexington Intl, LLC, is excited to announce they have received groundbreaking FDA Marketing Clearance for the HairMax LaserComb Lux 9 to treat female hair loss and promote hair growth. Included as a key part of the submission was a multi-center clinical study proving the efficacy and safety of the HairMax.

The Official FDA Clearance Letter can be viewed here;  
<http://hairmax.com/docs/hairmaxfdaclearance2011.pdf>

“Hair loss amongst women is a growing concern”, says Dr. Matt Leavitt, Medical Advisor to Lexington. “In the past, women had only one FDA Approved drug ingredient to treat their hair loss. Now they have a clinically proven viable alternative. Upon review of Lexington’s extensive clinical studies on female hair loss, the FDA has granted Clearance to this exciting new treatment option. I believe the HairMax will be able to offer help to the millions of women suffering from hair loss.”



The last hair loss treatment for women to be approved by the FDA was minoxidil, which came to market for females in 1988. The HairMax is now the first non-drug, home-use OTC medical device cleared to treat the estimated 80 million men and women suffering from hereditary hair loss.

The HairMax Lux 9 is indicated to treat Androgenic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2 or frontal and Fitzpatrick Skin Types I-IV.

Clinically Proven - The results of a double-blind, device-controlled clinical study conducted under Good Clinical Practices showed that 100% of subjects on the HairMax Lux 9 experienced hair growth at 6 months. Furthermore, over the same period of time, females using the HairMax Lux 9 grew an average of 20.5 hairs per square centimeter, which is considered medically and scientifically significant.

Most importantly, over 70% of the subjects using the HairMax Lux 9 reported improvement in thickness and fullness of their hair. No serious side effects occurred and there were no other types of side effects caused by the HairMax Lux 9 in the study.

The HairMax LaserComb Lux 9 clinical trial was conducted at five research locations in the United States. The investigators were, Janet Hickman, MD, Michael Jarrett, MD, David Goldberg, MD, Jose Mendez, DO, and Abe Marcadis, MD. The double blind study compared the HairMax Lux 9 to a control device so that the investigator, the subjects, nor the evaluator of the hair counts knew which device the subject was using.

The protocol for the study was approved by an IRB (Investigational Review Board) and monitored by a CRO (Contract Research Organization). The trials were listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) which is a registry of federally and privately supported clinical trials conducted in the United States and around the world.

Mr. David Michaels, Managing Director of Lexington said, “Female hair disorders, especially hair loss, negatively impact the lives of millions of women. User satisfaction with other treatments has been relatively low. A highly effective user-friendly product for hair growth remained an unmet need for women. With this FDA Clearance for the treatment of females, the HairMax will now offer effective relief to enrich the lives of both men and women with hereditary hair loss.”

**How Does the HairMax Work?** How does the HairMax LaserComb work so effectively? It harnesses the power and technology of laser light. The HairMax delivers safe and effective laser energy to stimulate dormant and active hair follicles. Lexington research supports the theory that low level laser energy is able to stimulate the production of ATP by releasing bound nitric oxide in the cellular respiratory chain which increases metabolic energy, promotes microcirculation, contributes to regulation of cellular apoptosis, and stimulates cell proliferation. Clinical evidence demonstrates reverse miniaturization, increase in number of hairs per follicular unit, and induction and prolongation of the anagen phase.



By using the HairMax men and women can experience positive results and feel better about themselves and how they look. The HairMax Lux 9 is easy to use. Just treat your hair for 11 minutes, 3 times a week, in the privacy and convenience of your own home.

**Safe to Use:** The HairMax Lux 9 complies with FDA requirements for laser safety. There has never been any reports of serious side effects occurring either in clinical trials or in the 10 years

the device has been on the market. The HairMax uses a patented technology to part the hair allowing the focused laser energy to reach the scalp. The laser is most effective when it has an unobstructed path directly to the hair follicle. Through extensive research, Lexington has determined the optimal wavelength and energy level needed to deliver maximum results. Lexington's continued dedication to innovation ensures that users are always receiving the latest in laser hair technology.

Randy Veliky, Lexington COO said. "The HairMax Lux 9 FDA Clearance now expands the options for the treatment of both male and female pattern hair loss. For the first time, the combination of our patented technology, state of the art design and the proven efficacy will help relieve the suffering of the millions of men and women with hair loss."

In April 2011, the FDA also granted Clearance for marketing for 3 new models of the HairMax LaserComb for male pattern baldness.

Since 2001, Lexington has completed a total of seven clinical studies with 460 subjects. All of the studies have demonstrated the efficacy and safety of the HairMax LaserComb family of FDA Cleared devices. These statistically significant clinical study results validate the fact that the HairMax should be considered as a first line treatment for appropriate people suffering from hereditary hair loss.

**About Lexington International, LLC** Based in Boca Raton, Lexington is a manufacturer and developer of advanced phototherapy devices for home use. Lexington International markets the only laser device that has published the results of the efficacy of the device in a peer review journal. The HairMax is also the first and only device of its kind with FDA Clearance for marketing. Over the past 10 years and in over 155 countries worldwide, Lexington has helped hundreds of thousands of individuals to treat their hair condition. For more information about the HairMax LaserCombs, before & after photos or to request a product sample for editorial review, please contact: [mediarelations@hairmax.com](mailto:mediarelations@hairmax.com)



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