HairMax LaserComb Announces Reaching 10 Year Milestone and 5 Years of Marketing as a Medical Device for Hair Loss - With Proven Efficacy and Excellent Safety Record

The HairMax LaserComb, for the treatment of certain classes of hereditary hair loss in men and women has reached a 10 year milestone with 5 years of marketing as a medical device with an excellent record of efficacy and safety. Since the HairMax was introduced, there has never been any reports of serious side effects occurring.

Boca Raton, FL (April 24, 2012) - Lexington Int'l is pleased to announce that a milestone has been reached in the ten years of marketing and five years of marketing of the HairMax LaserComb as an OTC medical device, the device has proven to be not only effective, but safe for hundreds of thousands of men and women around the world who have used it to treat their hair loss. The HairMax is the only laser phototherapy device to receive FDA 510(k) marketing Clearance; in 2007 for males and in 2011 for females for the treatment of androgenetic alopecia (pattern hair loss). In the over ten years of marketing the device (including five years as a medical device), there has never been any reports of serious side effects ever occurring.

With the increasing awareness and reports of safety issues with Propecia (finasteride) for the treatment of hair loss, there have been a number of labeling updates mandated by the FDA and other international regulatory bodies. This is an important contrast to the HairMax LaserComb with its excellent record of safety.

On April 11, 2012, the U.S. Food and Drug Administration (FDA) announced changes to the professional label for Propecia (finasteride 1 mg) to "expand the list of sexual adverse events reported to FDA as some of these events have been reported to continue after the drug is no longer being used (note that erectile dysfunction after stopping use of these drugs was added as a known event in 2011)" and the agency established this 'Questions and Answers: Finasteride Label Changes' web site:

http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm299754.htm

Since hair loss is an aesthetic condition, products for the treatment of hair loss should not cause further complications. The HairMax is effective when used alone and does not require the use of any drugs to be efficacious, which makes the HairMax an ideal first line non-drug choice for people with hereditary hair loss.

The HairMax LaserComb, is a home-use device which provides efficacy when used just 3 times a week for 8- 15 minutes per session depending on model. The HairMax LaserComb has also been studied extensively in 7 clinical trials with 460 subjects, where the device was proven to be consistently effective and safe with no serious side effects reported.

The first feasibility study of the device in was conducted in 1993 in Australia. In 2001, Lexington International was established in the United States to commercialize the device. In 2002 the HairMax LaserComb was introduced and the beginning of clinical studies began. In 2006, a major multi-center clinical trial was conducted in males with androgenetic alopecia (AGA). The results of this clinical trial, led in part to FDA marketing Clearance in 2007 as a medical device for the treatment of AGA in males. In 2011, based in part from the results of a multi-center clinical trial, the HairMax received FDA marketing Clearance for the treatment of androgenetic alopecia in females. Below is the official indication.

“The HairMax Advanced 7, Lux 9, Premium, 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.”

Mr. David Michaels, Managing Director of Lexington commented: “We are pleased to reach the ten year anniversary and the five year milestone in the marketing of the HairMax LaserComb as the only medical device indicated for treatment of hereditary hair loss in both men and women.” Mr. Michaels further stated: “Of utmost importance, is that the HairMax has helped hundreds of thousands of individuals with hair loss to successfully treat their condition and enrich their lives without any occurrences of serious side effects”.

About Lexington International, LLC

Based in Boca Raton, Lexington is a manufacturer and developer of advanced phototherapy devices for home use. The HairMax is also the first and only medical device with FDA Clearance for marketing for the treatment of hair loss and promotion of hair growth in both men and women. The HairMax is the only device of its kind to have results of the efficacy of the device published in a peer review journal. Over the past 10 years and in over 163 countries worldwide, Lexington Int., LLC has helped hundreds of thousands of individuals to treat their hair condition and enrich their lives. For more information, please visit: **(www.hairmax.com)**

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