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Hairloss Talk  
PO Box 211551 Chula Vista, CA 91921

Dear Sir or Madam:

We read with interest your article, Proven Treatments for Men's Hair Loss regarding the treatment of male pattern baldness. However, in the article it was stated that there are only two products on the market that are approved by the FDA for hair growth. This is *no longer correct* and we believe that this warrants the editing of your information.

In January 2007, our Laser Phototherapy Device, the HairMax LaserComb, received FDA Clearance for the 'Promotion of Hair Growth' in males with certain classes of Androgenetic Alopecia. The HairMax is a user-friendly, hand-held Class 3R Laser Phototherapy Device that contains nine individual laser beams encased in durable plastic housing. The HairMax is manufactured in the United States under strict quality control standards and is CE certified for laser safety.

The FDA clearance was based on the results of a double-blind, shamdevice, multi-centered clinical trial. After 6 months of therapy, the HairMax showed a mean change of +19.8 hairs/cm<sup>2</sup> vs. -7.6 hairs per cm<sup>2</sup> for the sham-device which was medically and statistically significant..

The FDA clearance of the HairMax makes it the only medical device cleared for this condition and only one of *three* products on the market that have FDA approval/clearance to treat male pattern baldness.

In general, users of the HairMax will notice some or all of the following benefits:

- New hair growth of dormant follicles
- A substantial decrease in hair fallout
- Increased speed of hair growth
- Increased manageability of the hair
- Overall better quality and condition of the hair

To further familiarize you with this important advance in the treatment of male pattern baldness, enclosed are the following:

- A Clinical Overview Brochure which provides a synopsis of clinical information on the HairMax LaserComb.
- A copy of the 510K Summary and FDA Clearance Letter.

(Our female study in Androgenetic Alopecia has just concluded and we will be submitting it to the FDA shortly. We are expecting FDA clearance to occur by the fourth quarter of 2008).

Finally, it is important for you to realize that there are no other laser photo therapy devices on the market that have FDA clearance to make claims related to hair loss and/or hair re-growth. The clearance of the HairMax DOES NOT translate to automatic approval of any other laser photo therapy devices. The FDA clearance is specific to the HairMax which is patented and utilizes *device specific* design and technology.

We hope that this information will be useful to you in your future commentary on hair loss treatments. Please do not hesitate to contact us if there is anything further you require.

Leonard Stillman  
Director of Professional Services