

## NPA Petitions FDA to Acknowledge the Benefits of Manual, Non-chemical Approaches and the LiceMeister® Comb for the Care of Children with Head Lice

Consumers, public health policy makers and school and child care administrators need to be informed that routine screening, early detection and manual removal of head lice and their eggs (nits) using a quality combing tool is critical to ensuring safe and hygienic resolution of an infestation.

BOSTON (PRWEB) February 13, 2018 -- The National Pediculosis Association (NPA), a non-profit 501(c)(3) organization dedicated to protecting children and their environment from the misuse and abuse of prescription and over-the-counter pesticide treatments for lice and scabies, announced today that it has petitioned the Commissioner of the Food and Drug Administration (FDA) to amend its website and other educational collateral so that combing, in general, and the FDA-accepted 510(k) LiceMeister® comb, in particular, are presented as valid options for the management and treatment of the communicable disease pediculosis capitis (head lice).

The NPA's petition is consistent with the FDA's goal to empower consumers and patients to make informed and effective health decisions, as stated by Commissioner Scott Gottlieb, M.D. in his blog post, "Looking ahead: Some of FDA's major policy goals for 2018." Currently, the agency offers extensive information about brand name chemical methods that can be used to treat children with head lice, but mentions combing only briefly and generically, without sufficiently explaining the value of combing or that all lice combs are not equivalent.

The benefits of combing and the LiceMeister comb are well documented.

Since its inception in 1983, the NPA has advocated for combing to remove lice and nits. In 1997, the NPA developed the LiceMeister comb, which features elongated stainless metal teeth precisely fixed in a hygienically-sealed handle. The comb can be sterilized for safe and repeated use, and in 1998, it was "accepted" by the FDA as a 510(k) medical device (FDA K981250).

The indicated use of the LiceMeister is for "routine screening, early detection [and] removal of lice and their eggs," which, when done thoroughly, effectively ends an infestation. That means the LiceMeister is a complete treatment that can either stand on its own as an alternative to pesticides and various chemicals or be used as a complement to other remedies.

When used routinely, combing allows parents to be the first to know their child is infested, discovering it early when there are fewer lice and nits to comb out. As reported by Mumcuoglu KY, et al, "Diagnosis of louse infestation using a louse comb is four times more efficient than direct visual examination and twice as fast. The direct visual examination technique underestimates active infestation and detects past, non-active infestations." In fact, because combing is so effective for screening and treatment, it has spawned a cottage industry of lice and nit removal services and has become an accepted method for data collection in scientific research studies.

When used as a complete treatment, combing can meet the health and medical needs of those who are most vulnerable to pesticides, while reducing the use of potentially harmful chemicals.



For example, in 2000, the NPA partnered with the Sanitation District of Los Angeles County and the City of Los Angeles Bureau of Sanitation in the Lindane Usage Reduction Project, which identified lindane-based lice treatments as the source of lindane pollution in the Los Angeles water supply. The LiceMeister comb and NPA's educational materials were critical features of this public health outreach project, which was recognized by the National Pollution Prevention Roundtable (NPPR) with its First Place Most Valuable Pollution Prevention (MVP2) Award honoring the most innovative and successful pollution prevention programs in the country. The project was credited as the first major program to convince physicians to change the medications they prescribe based on environmental concerns, and lindane was banned as a treatment for lice and scabies by California in 2002.

Subsequent research concluded that the elimination of lindane "was associated with a reduction in reported unintentional exposures, and did not adversely affect head lice [and scabies] treatment." (The U.S. Environmental Protection Agency (EPA) cancelled lindane's use in 2006. The FDA continues to allow the use of lindane for lice treatment although it requires a "black box" warning in the labeling to prescribers.)

In 2011, the LiceMeister raised the standard in lice combing tools around the world when it was featured as a lindane alternative at a global meeting of the Stockholm Convention. Since then, 179 countries prohibited lindane's use entirely, including pharmaceutical use.

The FDA needs to update its website and other educational collateral.

Despite the numerous benefits of combing and the LiceMeister comb, the FDA's website and educational collateral continue to prioritize pesticide or antibiotic formulations that put both the health of the person applying the treatment and the person receiving the treatment at risk. Pesticide exposure can lead to a myriad of serious medical and public health consequences, including but not limited to cancer, neurotoxicity, burning of the skin, breathing difficulties and behavior changes, along with pollution, lice resistance and chronic infestations that contribute to the communicability of lice to others. The recognition of pediculosis capitis as a public health issue has become increasingly important in recent years as schools relax their lice policies, allowing children to return to the classroom without requiring the removal of lice and nits.

Even in cases where chemical treatments are administered, the FDA recommends combing, but fails to help the consumer by not pointing out that combing tools can vary greatly. In its petition, the NPA requests that the information provided on combs and combing to be more specific given that the use of a quality comb can maximize treatment efficacy and minimize the overtreatment that can occur due to a panicked reaction to the presence of lice or as a desperate response to treatment failure.

"The FDA can do a better job of informing the public that combing is not only a valid treatment but an invaluable early detection tool," said NPA's President Deborah Altschuler. "Updating the FDA's website would help parents and others understand that the use of a quality comb to screen, detect and remove lice and nits (eggs) is a realistic, available and safe option for resolving an infestation."

## About The National Pediculosis Association:

Incorporated in 1983 and now in its 35th year, the National Pediculosis Association®, Inc. (NPA) is a 501(c)(3) non-profit volunteer organization, including scientific advisors dedicated to protecting children and their environment from the misuse and abuse of prescription and over-the-counter pesticide treatments for lice and scabies. Proceeds from the LiceMeister® comb allow the NPA to be self-sustaining and accomplish its mission.



For more, please visit <u>www.headlice.org</u>. The NPA website offers free educational information and downloads and provides a special section of information and activities designed by kids for kids. <u>http://www.headlice.org/kids/index.htm</u>



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