



NATIONAL PEDICULOSIS ASSOCIATION, INC.

1005 Boylston Street STE 343
Newton, MA 02461

website: <http://www.headlice.org>
Serving the Public Since 1983

February 6, 2018

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fischers Lane
Room 1061
Rockville, MD 20852

Attention: Commissioner Scott Gottlieb, M.D.

Dear Commissioner Gottlieb:

Attached please find a citizen's petition for your review. We thank you in advance for your consideration and look forward to your response.

Sincerely,

A handwritten signature in black ink, appearing to read "Deborah Z. Altschuler".

Deborah Z. Altschuler
President
National Pediculosis Association
npa@headlice.org

"Because it's not about lice, it's about kids."

Citizen Petition

Date: February 6, 2018

The undersigned submits this petition to request the Commissioner of Food and Drugs to amend its website and other educational collateral.

A. Action Requested

With this petition, the National Pediculosis Association, Inc. (NPA), a nonprofit 501(c)(3) organization, requests the Commissioner to update the FDA's website and other educational collateral so that combing, in general, and the LiceMeister comb, an FDA accepted 510(k) medical device, in particular, are presented as valid and listed options for the management and treatment of the communicable disease *pediculosis capitis* (head lice).

Currently, the FDA emphasizes chemical treatments for children with head lice and refers to these treatments by brand name. By contrast, lice and nit removal combs are referred to only briefly and generically, without attention to the proven methods and benefits of combing or the fact that all lice combs are not equivalent.

The NPA requests that the Commissioner update the FDA's website and other educational collateral so that the agency acknowledges (1) the benefits of combing and (2) that all lice combs are not equivalent. The NPA also respectfully requests that, to be consistent with the FDA's identification of chemical treatments by brand name, the agency's educational materials include mention of the LiceMeister comb by its brand name as well.

B. Statement of Grounds

In 1998, the LiceMeister comb was accepted by the FDA as a 510(k) medical device (FDA K981250) for the screening, detection and removal of lice and nits from the hair. With strategically-placed stainless metal teeth fixed in its hygienically-sealed handle, the LiceMeister has raised the standard for lice combing tools around the world and was featured as a lindane alternative at a global meeting of the Stockholm Convention in 2011 (Ashton 1).

But even so, the FDA has made insufficient effort to inform the public about the importance of this valuable tool for public health, the practicalities of combing or that combing is an accepted method of data collection in scientific research.

As Mumcuoglu, et al. reported in the medical literature, "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" (Mumcuoglu et al. 1). In addition, the 510(k) marketing description accepted by the

FDA states that the LiceMeister can “screen, detect and remove lice and nits,” effectively ending an infestation. That means the LiceMeister can either stand on its own as an alternative to chemicals or be used as a complement to other remedies. When used as an alternative, a quality comb can meet the health and medical needs for those who are most vulnerable to pesticide remedies—especially children, who are more susceptible than adults to diseases and toxic chemicals (American Academy of Pediatrics 4; Watnick 806; World Health Organization 6).

Despite the LiceMeister’s 510(k) medical device status and its numerous proactive treatment benefits, the FDA has not educated the public adequately about the importance of combing for the screening, early detection and manual removal of lice and their eggs. Instead, the FDA website and other educational collateral prioritize chemical formulations that put both the person applying the treatment and the person receiving the treatment at risk. Such products have proven less than 100% effective and contain chemicals, such as pesticides and broad-spectrum antibiotics, that can lead to negative medical and environmental consequences, including treatment failure, chronic infestations, communicability of lice to others, lice resistance, pollution and other adverse public health impacts. Even in cases where pediculicide treatments are administered, the removal of lice and nits by combing equalizes the efficacy of most pediculicides, enabling the consumer to protect against overtreatment and unnecessary exposure to potentially harmful chemicals. By using a non-toxic, reusable and non-consumable combing device, families can lessen, if not eliminate, the risks of adverse reactions to pesticide treatments. In addition, thorough combing mitigates chronic infestations, which in turn can minimize school and child care absences.

To its credit, the FDA acknowledges that chemical treatments are less than 100% effective, requires combs be included in the packaging of chemical treatments and has adopted a 2018 policy goal to empower consumers and patients to make more informed and effective health decisions—all of which bolster this request for action. While others may debate the importance of comb types, the NPA maintains that successful combing requires the standard of a quality combing device and that the public needs comprehensive and helpful treatment guidance (Devore e1360). Consumers, public health policy makers, and school and child care administrators need to be properly informed that manual removal of lice and their eggs (nits) is critical to ensure safe and hygienic resolution of an infestation.

C. Environmental Impact

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 [and scabies] 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 to inform the public and provide an alternative approach with education and comb. The project was recognized in 2001 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.” (Humphreys et al. 1) (The U.S. Environmental Protection Agency (EPA) cancelled lindane’s use in 2006. Following the Stockholm Convention in 2011, 179 countries prohibited lindane’s use entirely, including pharmaceutical use.)

The FDA allows the use of the chemical lindane as a second-line treatment and requires a “black box” warning in the labeling to prescribers. The FDA also allows the products Nix®, Rid®, Ulesfia®, Natroba® and Sklice®, as pediculicide treatment options for head lice. However, the FDA does not adequately address the environmental impacts associated with these remedies, nor does it track or warn the public of chemical-resistant lice.

Precision-designed combs serve the public health as the critical factor in resolving infestations safely and thoroughly with minimal use of chemicals and the environmental impacts associated with the manufacture, pharmaceutical use and disposal of pesticides. Therefore, the NPA respectfully requests that the FDA:

- Update its website and other educational collateral so that they better explain the benefits of combing and that all lice combs are not equivalent, and
- Include mention of the LiceMeister comb’s brand name, consistent with the FDA’s reference to chemical treatments by brand name, in order to inform consumers that the LiceMeister comb is among the head lice treatments available.

Both requests are consistent with the FDA’s 2018 policy goal to empower consumers and patients to make more informed and effective health decisions. As FDA Commissioner Scott Gottlieb, M.D. wrote in “Looking ahead: Some of FDA’s major policy goals for 2018:”

“Many of our agenda submissions are part of a broader effort to empower consumers and patients to make more informed and effective health decisions and ensure they have appropriate autonomy over their choices, while continuing to ensure the products they consume and use are safe and effective. Consumers tell us that they want this information. We also know that

consumers who have access to more diverse, safe and effective options – and who have improved information about those choices – make better, more cost-effective decisions.”

D. Economic Impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition which are unfavorable to the petition.



Deborah Z. Altschuler, President

(Signature)

National Pediculosis Association®, Inc

(Name of petitioner)

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Works Cited

- American Academy of Pediatrics. "Pesticide Exposure in Children." *Pediatrics*, 26 Nov. 2012, doi:10.1542/peds.2012-2757.
- Ashton, Melanie. "Stockholm Convention Launches POPs-Free Initiative." SDG Knowledge Hub, 21 Apr. 2011, sdg.iisd.org/news/stockholm-convention-releases-launches-pops-free-initiative/.
- Devore, Cynthia D., et al. "Head Lice." *Pediatrics*, vol. 135, no. 5, May 2015, doi:10.1542/peds.2015-0746.
- Humphreys, Elizabeth H. et al. "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts." *Environmental Health Perspectives*, 116.3 (2008): 297–302. PMC. Web. 28 Nov. 2017, doi:10.1289/ehp.10668.
- Mumcuoglu, Kosta Y., et al. "Louse Comb Versus Direct Visual Examination for the Diagnosis of Head Louse Infestations." *Pediatric Dermatology*, vol. 18, no. 1, 2001, pp. 9–12, doi:10.1046/j.1525-1470.2001.018001009.x.
- National Pollution Prevention Roundtable. "National Pollution Prevention Roundtable's 2001 Most Valuable Pollution Prevention Award Ceremony." www.headlice.org/news/2001/nppr.htm.
- Watnick, Valerie. "Pesticides and Children: Unwitting Participants in Experimentation." *Cardoza Journal of Law & Gender*, vol. 13, June 2008, pp. 801-23, www.cardozolawandgender.com/uploads/2/7/7/6/2776881/13-4_watnick.pdf.
- World Health Organization. 2011, Summary of Principles for Evaluating Health Risks in Children Associated with Exposure to Chemicals, www.who.int/ceh/health_risk_children.pdf.