NPA
NATIONAL PEDICULOSIS ASSOCIATION, INC.
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Serving the Public Since 1983

August 19, 2002

Lee Lemley, Policy Analyst
Executive Operations Staff
Office of Executive Programs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Lee:

The FDA's wording in its Talk Paper on lindane labeling dated 4/3/96 (T96-24) continues to jeopardize the public health in 2002. Recommendations that lindane follow earlier pesticide use is without consideration for the varied vulnerabilities of populations exposed to different pediculicide formulations in uncontrolled and indeterminate quantities. Pediculicide treatments put both the person applying the treatment and the person receiving treatment at risk.

The FDA acknowledged, **"...parents may be inclined to overuse the product in their zeal to treat children as quickly as possible. This increases the amount of Lindane to which children are exposed and raises the likelihood for adverse reactions to occur."**

With the risks of lindane misuse established, this same publication recommended labeling changes that **"encourage lindane's use only for patients who have either failed to respond to adequate doses, or are intolerant of, other approved therapies."** This directive encourages over-treatment and adverse events by recommending the most potentially toxic of pediculicides, status post exposure to any variety or combination of other pesticide formulations that have failed.

- FDA's pediculicide approvals are not based on multiple or concomitant use of one pesticidal formulation with another.

- Pesticides accumulate in the body.

- FDA pediculicide safety studies do not account for additional or simultaneous dermal and respiratory pesticide exposures and interactions via lice sprays marketed in tandem with pediculicide shampoos and lotions.

- Repeat treatment exposures are predictable given that none of the available products are 100% effective. Manufacturers account for this by recommending a second pediculicide application in 7-10 days.

- Products are approved without required periodic reassessment for the development of lice resistance, a predictable phenomenon with pesticides. However lice resistance has been scientifically documented for the most widely used products, resulting in misuse and

abuse of pediculicides. Treatment failure no matter what the cause -- encourages more treatments. Products that do not live up to claims create consumer confusion, frustration with ongoing infestations, pediculicide overuse and overexposure. This scenario is commonly played out and would be the likely population desperately seeking a prescription.

- Consumers are misguided to believe a doctor's prescription for lindane (or malathion) will be safer, better, and more effective.

- Physicians often perceive head lice as a nuisance disease and are unlikely to assess the extent or various ways in which a child or an entire family has been over-exposed to potentially harmful pediculicides. Physicians and patients both need warnings to avoid unnecessary additional exposures. Manual removal is a safe option when chemicals have failed.

Lindane and malathion are two serious pesticidal agents currently being recommended as the answer to treatment failure and resistance issues. Lindane can pose serious neuro-toxic, blood-related and environmental health risks for humans. The Agency For Toxic Substances' provides an extensive toxic profile on malathion but reports limited scientific studies on its safety and health risks to children.

The NPA strongly urges that these issues are respectfully considered in the current FDA assessment for possible revisions of pharmaceutical labeling for lindane.

Sincerely,

Deborah Z. Altschuler
President

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

Enclosures:

FDA Talk Paper
NPA Alert
Why a Non Chemical Approach