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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane – Rm. 1061  
Rockville, MD 20852

Response to proposed rule on: Pediculicide Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

21 CFR Part 358  
Docket No. 02N-0058  
RIN 0910-AA01

The National Pediculosis Association (NPA) a non-profit 501(c)(3) corporation is providing the following comments in opposition to the use of environmental lice sprays as noted on Page 17 of the Monograph. Additional comments on other sections of the Monograph will be submitted under separate cover/or will also be submitted.

The directive on Page 17 states:

- ...disinfect hats, hair ribbons, scarves, coats, towels and bed linens by machine washing in hot water...then using hottest dryer cycle for at least 20 minutes...
- ...**items that cannot be washed, dry-cleaned or stored may be sprayed with a product designed for this purpose.**
- ...vacuum all carpets, mattresses, upholstered furniture, and car seats...

We feel these comments are ambiguous and confusing. The environmental lice sprays are marketed for bedding and furniture (as stated on the labels); however, the Monograph recommends treatment of bedding and furniture by vacuuming thus eliminating any need for use of sprays.

Just about every OTC pesticide shampoos brand offers an environmental lice spray. The prominence of these sprays on the drug store shelf sends a message to the consumer that they are necessary.

Lice sprays are reportedly inexpensive to produce and therefore very profitable. Frantic consumers are known to purchase several cans at a time figuring one won't be enough for all the bedding, furniture and rooms in the house.

Although the information on spray labels advise those with asthma or severe allergies to "consult their doctor before using this product and have someone else apply this product," there is no warning for the kids with asthma or allergies, whose beds will be sprayed. There is however an ironic general directive to "Keep out of the reach of children."

The safe alternative – as noted in the Monograph - is the use of the household vacuum. Vacuuming is effective, realistic, practical, and safe and a readily available action to take for areas such as furniture, bedding, car seats, stuffed animals, etc. Vacuuming also eliminates the outdated labor-intensive bagging of such items.

- The harmful effects of pediculicide sprays (including eye and respiratory risks) apply not only the children but also to the parent doing the spraying and household pets.
- Young children, the age group most susceptible to head lice, often have mothers who may be pregnant or nursing yet the sprays come with no warning for these mothers or higher risk groups. The National Coalition Against the Misuse of Pesticides (NCAMP) says there is no safe way for a nursing mother to apply or spray pesticides, let alone protect her baby from the environment or very real possibility of contaminated breast milk.
- Lice sprays are marketed to be used in conjunction with lice shampoos, and therefore significantly increase the insecticide exposures without any regard for combined effects, cumulative absorption or safety.
- Lice sprays for bedding and furniture are unique in that they are regulated by the EPA but packaged with FDA regulated pesticide shampoos and lotions.
- Pediculicidal sprays have ingredients that become more toxic in their vaporized state.
- The ineffectiveness of lice sprays is documented in scientific studies of lice resistance to permethrin (the only active ingredient in the sprays) and cross-resistance to other pesticides found in the most widely available treatment products.
- Schools that spray pesticides for lice add risks for their student population given that parents are often not informed of the school spraying and repeat similar actions within the home.
- Cumulative risks also occur when schools and other institutions spray for other pests such as ticks, mosquitoes and roaches.
- Selling pesticide sprays for children's bedding risks children's health and exploits their parents and their pocketbooks at a time of high anxiety. The more conscientious the unwarned parents, the more likely it is that they will spray everything in the house.

Ours is a strange society where we are required to post signs on lawns after they have been treated with pesticides to be sure children do not play there...while pesticide sprays continue to be sold for children's beds.

The National Pediculosis Association strongly suggests that the FDA acknowledge the dangers and ineffectiveness of lice spray and delete any reference to them in the final Monograph.

