



12 November 2013

FDA ADVISORY  
No. **2013-051**

**SUBJECT: CONSUMER WARNING AGAINST UNREGISTERED ALLERCON  
DUST MITES SPRAY**



Unregistered Allercon Dust Mites Spray, claiming to be an Anti-Allergy Spray, has been found in shelves of big supermarkets. The manufacturer or distributor of the product is unknown, but the name Fourth Horizon Corp., Q.C. Philippines is printed on the label. Upon verification, Fourth Horizon Corp. has no FDA License to Operate. The supplier of the product is in violation of the provisions of Republic Act No. 9711, otherwise known as the FDA Act of 2009, which prohibits the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded.

Aside from being an unregistered health product, the product label is misleading. Among others, the following statements can be read from the label *"Dust mites reproduce very rapidly and should be contained immediately. They can only be eradicated and prevented by the active ingredient in ALLERCON DUST MITES SPRAY. (Tannic Acid 2%)"*. Tannic acid is a synthetic product that comes from tannin, an astringent compound that can break down some proteins. Tannic acid does not kill the mites, but it may neutralize the allergenic protein from the fecal wastes of dust mites. In order to make the claim of "eradicating and preventing" dust mites, the applicant should apply for a Certificate of Product Registration and submit a bioefficacy study to FDA for evaluation.

In the United States, there are no pesticides currently labeled products for killing dust mites. Killing dust mites that are microscopic non-parasitic arachnids will not really help since dead microscopic mites would actually release the protein that causes allergy. Placebo-controlled study of the mite allergen-reducing effect of tannic acid plus benzyl benzoate on carpets in homes of children with house dust mite sensitization and asthma, was published in February 2002 issue of peer-reviewed journal, the Pediatric Allergy and Immunology. Lau S, et al. concluded that the slight mite allergen reduction on carpets achieved by the treatment







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with 1% tannic acid is unlikely to achieve clinical benefit either in the treatment of mite-sensitive patients, among others. (<http://www.ncbi.nlm.nih.gov/pubmed/12000496>).

There is no declaration of the manufacturer and formulation (list of ingredients) on the product label. Chances are, the product does not contain any active ingredient and that the consumers will be paying only for the 98% inactive ingredient(s), possibly scented water.

House dust mites are microscopic, eight-legged arachnids, distinct from the six-legged insects, are not parasitic and do not bite. They do not burrow under the skin, like scabies mites or live in skin follicles, like skin follicle mites. Dust mite and its feces are known sources of allergens. Symptoms associated with dust mite allergies, which are really uncommon in the Philippines, include sneezing, itchy, watery eyes, nasal stuffiness, runny nose, stuffy ears, respiratory problems, eczema and (in severe cases) asthma. Allergies from dust containing allergens from cat and dog hair, cigarette ash, cockroach droppings, mold spores and pollen are more common in the country.

From the public health standpoint, household and urban pesticides need to be registered with the FDA to ensure the safety of the product to the consumers, applicators and the environment. Impurities formed during manufacture of the pesticide or by interaction in unstable formulations can increase product toxicity to humans and the environment. Applying products that are lower in active ingredient content than declared could result in monetary loss and application of a sub-lethal dose of pesticide, leading to ineffective control and promotion of the development of resistance (WHO).

The FDA Inspectorate is now conducting investigation to verify the source of the product in the market and will undertake appropriate legal action.

Consumers are advised to check if health products are registered with the FDA by logging in the FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)) and type in the name of the product in the Search bar. To report unregistered products or adverse reaction after using health products, kindly email us at [report@fda.gov.ph](mailto:report@fda.gov.ph) or through the eReport platform at [www.fda.gov.ph](http://www.fda.gov.ph). For more information and clarification, kindly email us at [info@fda.gov.ph](mailto:info@fda.gov.ph).

  
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