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September 28, 2004

Division of Dockets Management

Docket No. 2004N-0289

5630 Fishers Lane, Room 1061

Rockville, MD 20852

Dear Reader,

On behalf of the American Academy of Allergy, Asthma & Immunology, a professional organization with over 6,000 members representing allergists and immunologists, I am writing in response to the August 2, 2004, Federal Register entry in reference to "Cold, Cough, Allergy, Bronchodilator, and Anti-Asthmatic Drug Products for Over-the-Counter Human Use: Proposed Amendment of Final Monograph for Over-the-Counter Nasal Decongestant Products" call-for-comments to remove the partial labeling indication "for the temporary relief of nasal congestion associated with sinusitis," which will also prohibit the use of the terms "sinusitis" and "associated with sinusitis" elsewhere on the labeling.

I am writing to state the proposal is reasonable, appropriate and a step in the right direction. However, many of the remaining claims do not appear to be backed by evidence, especially "helps decongest sinus openings and passages." The Sinusitis Committee of the AAAAI recommends that any claim of efficacy should be supported by evidence-based published literature.

I want to thank the FDA for soliciting the public and professional community for comments on these labeling changes.

I look forward to the final FDA decision about this proposal.

If you have questions, please contact me at 303-795-8177.

Sincerely,

Allen D. Adinoff, MD, FAAAAI  
AAAAI 2004 Sinusitis Committee Chair

Cc Michael Schatz, MD MS, FAAAAI, AAAAI President  
Anne Marie Irani, MD, FAAAAI, AAAAI Rhinitis, Sinusitis and Ocular  
Diseases Interest Section Chair

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