

From: John Georgitis  
Sent: Wednesday, May 02, 2001 12:45 PM  
To: Sandra Titus  
Subject: OTC ruling relating to Non-Sedating Antihistamines

Dear Sandra,

I am replying about the possible ruling for non-sedating antihistamines becoming OTC. As a practicing board certified allergist-immunologist and an active clinical researcher of atopic diseases, this ruling will clearly interfere with management of patients with allergic and chronic rhinitis. Foremost, these patients due to complications of the disease, effect on quality of life, and social stigmata of chronic rhinitis, by making an effective therapy for rhinitis available on an OTC basis will give the message to patients that they do not need to be managed by a physician. Secondly, from a patient perspective, a large portion of the public with chronic rhinitis will be unable to pay out of pocket for these medications once they are no longer covered by insurance carriers. Thirdly, these products do have a low incidence of side effects but side effects none the less which patients need to be made aware of - if they are OTC, who will do this patient education? Fourthly, if these are made OTC, the FDA should seriously consider making ALL current OTC antihistamines as prescription medications due to their high incidence of sedation and effect on work performance. Maybe this should be the FDA ruling to make all antihistamine products as prescription for patient education aspects. Lastly, in this current economic climate, we need not put any further burden on the public and since 20% or more of the population suffer from chronic rhinitis, this ruling will have a widespread effect on the current economic situation in the US.

Thank you.

Sincerely yours,

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