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## Pfizer Consumer Healthcare

November 1, 2004

Division of Dockets Management  
5630 Fishers Lane Rm. 106  
Rockville, MD. 20852

Re: **Docket No. 2004N-0289**  
**RIN 0910-AF34**  
**Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Final Monograph for Over-the-Counter Nasal Decongestant Drug Products**

Dear Sir or Madam:

In the August 2, 2004 Federal Register, the Food and Drug Administration (FDA) published and solicited comments on a Proposed Rule entitled "Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Final Monograph for Over-the-Counter Nasal Decongestant Drug Products". The intention of the Proposed Rule was to remove the indication "for the temporary relief of nasal congestion associated with sinusitis" and to prohibit use of the terms "sinusitis" and "associated with sinusitis" elsewhere on the labeling.

FDA promulgated the proposed rule out of concern that a consumer might use an OTC nasal decongestant drug product (oral or topical) to treat symptoms associated with sinusitis, rather than seeking medical evaluation and definitive treatment. FDA believes that this delay could result in a lost opportunity for early diagnosis of another serious medical condition in a consumer with symptoms similar to sinusitis. FDA notes that a consumer with bacterial sinusitis or sinusitis with asthma could worsen their condition by delaying treatment.

Pfizer Consumer Healthcare supports regulatory action to add or remove monograph conditions when the action is supported by valid scientific data. As explained further below, we do not feel that this action standard has been met in the current proposed rule. We believe that the agency should be compelled to provide valid scientific data prior to taking the action noted in the proposed rule.

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### **Sinusitis and the OTC Nasal Decongestant Final Monograph; Bacterial Resistance**

Sinusitis is an infection or inflammation of the continuous sheet of mucosal epithelium that lines the sinuses, ostial channels and nasal airways. The hallmark early symptoms of sinusitis are pain and/or pressure in some areas of the face (forehead, cheeks or between the eyes) with nasal congestion. This inflammation can lead to blocked drainage of the sinuses followed by a build up of thick mucus in the sinuses that can lead to a bacterial infection. At the stage of bacterial infection additional symptoms can occur, including: thick green or yellow nasal mucus discharge, and fever.

Physician intervention is necessary for adequate treatment of a sinusitis episode that includes a bacterial infection. Standard treatment consists of an antibiotic for the bacterial infection, if one is present, and other medications as necessary for the associated pain and nasal congestion. A consumer with recurrent sinusitis must continue to consult their physician for each episode due to the need for a prescription antibiotic to treat recurrent acute episodes that are associated with bacterial infection.

The OTC Nasal Decongestant Final Monograph does not include a provision for the "temporary relief of sinusitis". However, under the monograph, a nasal decongestant drug product can claim to provide "temporary relief of nasal congestion *associated with sinusitis*" (emphasis added).<sup>1</sup> The condition "sinusitis" is not further defined in the consumer or professional labeling allowed under the monograph and is therefore not further defined in the labeling of a product containing an over-the-counter nasal decongestant. Accordingly, it is not likely that consumers would interpret the indications specified in the labeling to mean that the product can be used for self-treating "sinusitis". A consumer would know that they have sinusitis only after intervention by a physician. A consumer with recurrent sinusitis may be able to recognize the signs and be able to begin to treat the nasal congestion with an over-the-counter nasal decongestant as they seek medical intervention.

In the worst case scenario, a consumer may be unaware that they have sinusitis and treat the associated nasal congestion, with a nasal decongestant drug product thereby allowing the sinusitis to progress in some cases. The labeling of OTC nasal decongestant drug products is required to contain a statement warning consumers to stop taking the medication and consult a doctor if their symptoms do not improve within 7 days or if the symptoms are accompanied by fever. Therefore, a consumer following the product labeling would discontinue use of the nasal decongestant drug product if they experienced fever (a symptom associated with a bacterial infection in sinusitis) or if the condition lasted for more than 7 days (inflammation of the paranasal sinus mucosa in sinusitis commonly lasts up to twenty-one days).

Bacterial resistance is a growing problem with the current arsenal of antibiotics. If the proposed rule is put into effect, there will be no OTC labeled product that can be used in some capacity for the condition sinusitis, leaving the consumer only with the option of medical intervention to begin treatment of their symptoms. If consumers' are limited with only the option to seek

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<sup>1</sup> 21 CFR § 341.80(b)(1)(iii)

medical intervention, there will likely be a greater demand from consumers' to receive antibiotics earlier on and for episodes where they are not necessarily needed. A consumer who is going through the inconvenience associated with scheduling an office visit is more likely to demand the strongest treatment available, an antibiotic, as is documented throughout the literature. With greater demands for antibiotics, there will invariably be more cases where antibiotics are inappropriately prescribed, further worsening the public health issue of antibiotic resistance.

In summary, it is our contention that the current labeling does not serve to delay a consumer in seeking appropriate treatment for sinusitis. The current labeling notes that nasal decongestants may be used to relieve nasal congestion associated with sinusitis but does not provide any definition of the signs or symptoms of sinusitis. Additionally, the labeling directs a consumer to stop use of the product and consult their doctor if nasal congestion is associated with fever or lasts longer than 7 days. Given that the sinusitis symptoms that are associated with a bacterial infection are distinguishable from nasal congestion (purulent nasal discharge, fever, facial pain and symptoms lasting longer than 7 days) we believe that a consumer experiencing bacterial sinusitis will seek professional treatment and will not resort to the sole continued use of a nasal decongestant to treat only one of the symptoms of their condition. In addition, limiting a consumer's option to begin treatment of sinusitis symptoms only with medical intervention may lead to greater demand for antibiotics, inappropriate prescribing and further worsening the public health issue of antibiotic resistance.

### **Efficacy support**

Under the OTC monograph review process, nasal decongestants are category I for the treatment of nasal congestion associated with sinusitis. FDA has not produced clinical efficacy studies for any single nasal decongestant nor have they produced data to show that, as a class,  $\alpha$ -adrenergic decongestants are not appropriate for relief of nasal congestion associated with sinusitis.

Despite the older references <sup>2,3</sup> cited by the agency, current consumer-orientated medical information continues to note that nasal decongestants are recommended by physicians for nasal congestion associated with sinusitis. As an example, the American Academy of Otolaryngology-Head and Neck Surgery notes that oral and topical nasal decongestants may be used to alleviate nasal congestion associated with sinusitis.<sup>4</sup> The National Institute of Allergy and Infectious Diseases (National Institutes of Health, US Department of Health and Human Services) notes that physicians may recommend decongestants to reduce congestion.<sup>5</sup> The American Academy of Allergy, Asthma & Immunology notes that in addition to prescribing an antibiotic to control

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<sup>2</sup> Parameters for the Diagnosis and Management of Sinusitis, supplement to *The Journal of Allergy and Clinical Immunology*, 102 (6 Part 2): S107-S144, December 1998.

<sup>3</sup> American Academy of Pediatrics Subcommittee on Management of Sinusitis and Committee on Quality Improvement. "Clinical Practice Guideline: Management of Sinusitis." *Pediatrics*. 108(3): 798-808, 2001.

<sup>4</sup> [http://www.entnet.org/healthinfo/sinus/sinus\\_questions.cfm](http://www.entnet.org/healthinfo/sinus/sinus_questions.cfm) : [http://www.entnet.org/healthinfo/sinus/antibiotics\\_sinusitis.cfm](http://www.entnet.org/healthinfo/sinus/antibiotics_sinusitis.cfm).

<sup>5</sup> <http://www.niaid.nih.gov/factsheets/sinusitis.htm>

the bacterial infection, physicians may prescribe a medication such as a decongestant to reduce blockage.<sup>6</sup>

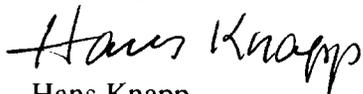
### **Conclusion**

In conclusion, while Pfizer Consumer Healthcare supports regulatory action to add or remove monograph conditions when the action is supported by valid scientific data, we do not feel that this action standard has been met in the current proposed rule. We believe that the agency should be compelled to provide valid scientific data prior to taking the action noted in the proposed rule.

Pfizer Consumer Healthcare appreciates the opportunity to submit comments in response to this proposed rule. We believe that our input into the proposed rule is very important and should be considered as the agency reviews comments to this proposed rule.

If you have any questions regarding the content of this submission, please contact the undersigned at 973-385-7250.

Sincerely,



Hans Knapp

Director, Regulatory Affairs  
Pfizer Consumer Healthcare

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<sup>6</sup> <http://www.aaaai.org/patients/publicedmat/tips/sinusitis.stm>