

Bayer Statement on FDA's proposed order ending use of oral phenylephrine as OTC monograph nasal decongestant active ingredient

“While we continue to stand behind the science supporting the efficacy of phenylephrine, we will review the FDA's proposed order on oral PE and consider the public comment period. As we enter the next allergy, and cough and cold season, Bayer has a variety of options including Afrin, Claritin D and Alka-Seltzer Plus to offer relief from the symptoms of allergy, cough and colds that US consumers may be experiencing.

“FDA has repeatedly concluded that over-the-counter oral PE is safe and effective, and it remains the only oral non-prescription medicine Generally Recognized as Safe and Effective (GRASE) today for the treatment of nasal congestion that is available without purchase restrictions. The scientific evidence supporting oral PE includes nearly five decades of rigorous scientific study and two prior FDA expert advisory committees. In-market consumer satisfaction also underscores its efficacy and the importance of continued over-the-counter access to PE. Bayer's highest priority is the safety and effectiveness of its products.

“The FDA's decision applies to the United States only. Outside the US, phenylephrine-containing Bayer products remain available in all countries where they currently have marketing authorization.”

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