FDA Proposes Removal of OTC Oral Phenylephrine From Cough/Cold Products

Evidence shows that the agent is not an effective nasal decongestant.

The FDA proposed the removal of oral phenylephrine (Sudafed PE; Johnson & Johnson) as an active ingredient in OTC drug products for the temporary relief of nasal congestion. The proposal is based on extensive review by the agency, which found that oral phenylephrine is not effective for this use.

“It is the FDA’s role to ensure that drugs are safe and effective,” said Patrizia Cavazzoni, MD, director of the FDA’s Center for Drug Evaluation and Research (CDER). “Based on our review of available data, and consistent with the advice of the advisory committee, we are taking this next step in the process to propose removing oral phenylephrine because it is not effective as a nasal decongestant.”

The FDA requested public commentary on the proposal before finalizing the removal of OTC oral phenylephrine from pharmacy shelves. Image Credit: © ColleenMichaels - stock.adobe.com

Phenylephrine is a common ingredient found in OTC allergy and cold medications thought to relieve congestion by reducing inflammation of the blood vessels in nasal passages. It is found in various well-known OTC medications, including NyQuil, Benadryl, Sudafed, and Mucinex.

Some of these products contain oral phenylephrine as a single active ingredient while others contain other active ingredients. According to the FDA, phenylephrine does not affect the effectiveness of other active ingredients. The proposed order is based on the effectiveness of oral phenylephrine, not its safety profile, meaning companies are permitted to continue marketing these products.

In September of 2023, the FDA held a Nonprescription Drug Advisory Committee meeting to discuss the ‘Generally Recognized as Safe and Effective’ status of oral phenylephrine as a nasal decongestant, which was prompted by a petition from researchers at the University of Florida. Based on existing scientific data, they concluded that oral formulations of phenylephrine are ineffective at both standard and higher doses. Additionally, only a small amount of the agent can make it to the nose.

Pulling oral phenylephrine could have significant financial consequences for CVS and Walgreens, who sold 242 million bottles of phenylephrine-containing drugs in 2022, generating almost $1.8 billion in revenue. Consumers may also be affected due to preference of oral decongestants over nasal sprays, based on survey data from the Consumer Healthcare Products Association.

“Consumers should know that a range of safe and effective drugs and other treatments is available to temporarily relieve congestion symptoms due to allergies or a common cold,” said Theresa Michele, MD, director of the Office of Nonprescription Drug Products in CDER. “Consumers can also talk to their doctor or pharmacist about ways to treat these symptoms.”

The FDA requested public commentary on the proposal before finalizing the removal of OTC oral phenylephrine from pharmacy shelves. If the comments support the evidence-based findings, a final order will be issued. Manufacturers will be

given time to either remove or reformulate drugs containing oral phenylephrine from the market. Consumers are encouraged to explore alternative options and consult health care providers or pharmacists for effective relief.

REFERENCES

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