U.S. FDA proposes ending use of popular decongestant present in cold medicines

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Bengaluru: The U.S. Food and Drug Administration has proposed to remove oral phenylephrine, widely used in cold and cough syrups, as an active ingredient in over-the-counter drugs for nasal congestion, stating it is not effective, the health regulator said on Thursday.

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Last year, an outside panel of experts unanimously voted against the effectiveness of orally administered phenylephrine as a nasal decongestant, adding that no more trials were required to prove otherwise.

Companies such as Procter & Gamble and GSK were among several accused in lawsuits of deceiving consumers about cold medicines containing the ingredient.

The FDA is now seeking public comments on this proposed order.

For now, companies may continue to market drug products containing oral phenylephrine as a nasal decongestant.

However, the FDA said it would provide manufacturers with appropriate time to either reformulate drugs containing oral phenylephrine or remove such drugs from the market.

The Consumer Healthcare Products Association said in a statement that it was "disappointed in FDA's proposal to reverse its long-established view of oral phenylephrine." The association added that it would review the proposed order and submit comments accordingly.

Tylenol maker Kenvue, GSK, Haleon , and Procter & Gamble did not immediately respond to Reuters' request for comment. (Reporting by Sriparna Roy, additional reporting by Sneha S K, in Bengaluru; Editing by Krishna Chandra Eluri and Tasim Zahid)

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