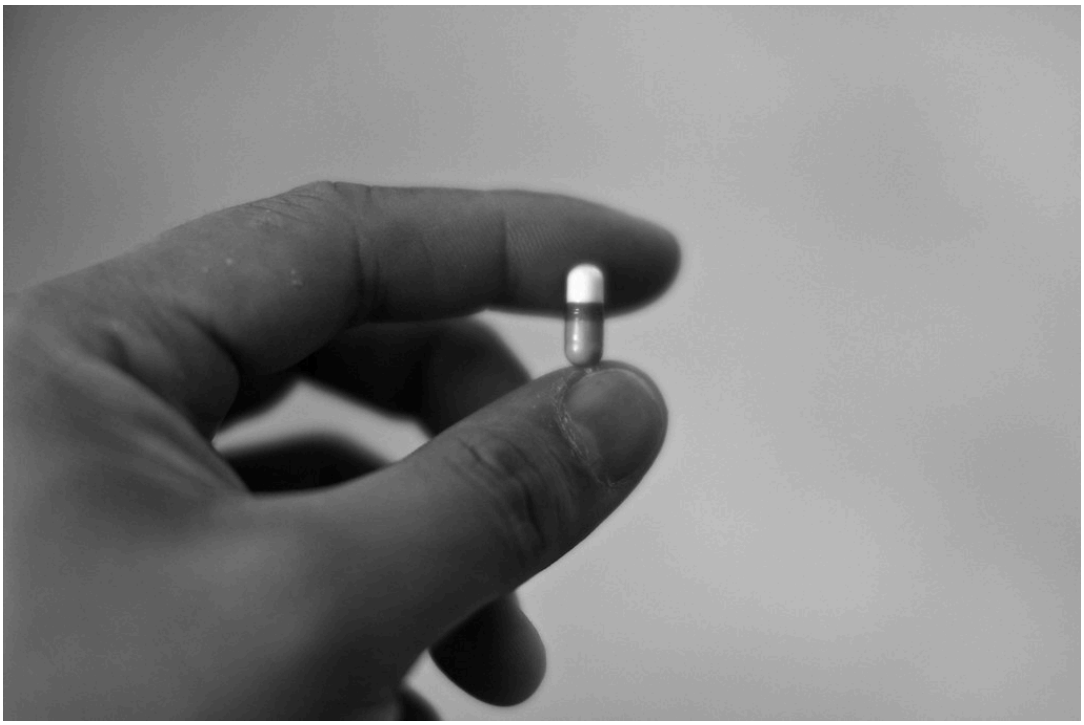
PHARMAMAG

FDA to Remove Ineffective Cold Medicine Ingredient from Shelves



by Avi Balani on November 27

As winter takes hold across much of the United States, many households are bracing for the familiar cold and cough season. For decades, consumers have turned to over-the-counter medications to manage symptoms like nasal congestion, often assuming that these remedies are both safe and effective. However, the Food and Drug Administration (FDA) recently announced a groundbreaking decision that could reshape cold and flu treatments. The FDA plans to remove phenylephrine, a widely used ingredient in many popular cold medicines, citing

its ineffectiveness. This proposal, which has been in the works for years, could go into effect as early as next year.

Phenylephrine is a mainstay in familiar brands such as NyQuil, Benadryl, and Sudafed PE. However, studies reveal that it is not effective when taken as a pill or syrup. Unlike pseudoephedrine, which was largely replaced by phenylephrine in over-the-counter medicines after being moved behind pharmacy counters, phenylephrine cannot provide meaningful relief for nasal congestion. According to Dr. Randy Hatton, a professor at the University of Florida College of Pharmacy, the problem lies in its poor absorption. "It is absorbed in less than 1% of the dose that it's given. And that's why it doesn't work," Hatton explained during a recent interview.

Phenylephrine became prominent in cold and flu medicines after concerns arose over pseudoephedrine's use in the illegal production of methamphetamine. In response to these concerns, pseudoephedrine was restricted to behind-the-counter sales, requiring consumers to request it directly from a pharmacist. To maintain convenience for consumers, manufacturers reformulated many medications, substituting phenylephrine for pseudoephedrine. However, as phenylephrine gained popularity, patients and researchers began questioning its effectiveness.

Dr. Hatton and his colleague Dr. Leslie Hendeles have raised concerns about phenylephrine for over 20 years. Their research shows that despite being considered safe, phenylephrine is ineffective enough to justify its continued presence on the market. “Drugs on the market in the United States, whether they're over-the-counter or prescriptions, have to be both safe and effective. And oral phenylephrine is ineffective,” said Hatton.

The FDA’s proposed ban is based on its commitment to ensuring that medications meet safety and efficacy standards. While phenylephrine is harmless when taken in standard doses, its ineffectiveness makes it an unsuitable option for consumers seeking relief. Removing it from shelves would align with the FDA’s mission to maintain high standards for all approved medications.

For individuals seeking alternatives to phenylephrine-containing products, Dr. Hatton suggests several options:

- **Pseudoephedrine:** This medication remains the most effective oral decongestant for nasal stuffiness. Although it is now kept behind pharmacy counters, it does not require a prescription. Most consumers can obtain it quickly by asking a pharmacist.
- **Nasal Sprays:** For those willing to use nasal sprays, products like Afrin or Sinex 12 Hour, which contain oxymetazoline, are highly effective. However, Hatton advises limiting their use to three to five days to avoid rebound congestion.

Importantly, Dr. Hatton warns against taking higher doses of phenylephrine in an attempt to achieve better results. Many over-the-counter cold medicines combine phenylephrine with other drugs like acetaminophen, which can be dangerous if taken in excessive amounts.

The FDA’s move has sparked a larger discussion about outdated or ineffective medications still available on the market. Hatton notes that phenylephrine is not the only over-the-counter drug

that may need reevaluation. “Some of those old products that were approved using science from decades ago are likely ineffective,” he said. Proper scientific review could prevent consumers from wasting money on treatments that fail to deliver promised benefits.

Critics of the FDA’s decision argue that removing phenylephrine limits consumer choice. However, Hatton refutes this claim, emphasizing that choice should involve effective options. “Why would somebody want the choice of something that does not work?” he asked. By removing ineffective products, the FDA aims to provide consumers with better access to medications that meet modern standards of safety and efficacy.

The FDA’s proposed removal of phenylephrine from over-the-counter cold medicines marks a significant step in ensuring that all available treatments are both safe and effective. For consumers, this decision highlights the importance of understanding the science behind commonly used medications. As the cold season approaches, individuals are encouraged to explore proven alternatives, such as pseudoephedrine or nasal sprays, to manage their symptoms effectively. Ultimately, this move reinforces the FDA’s role as a gatekeeper for public health, ensuring that every product on the market serves its intended purpose.