FDA rules TODAY that ingredient in Benadryl and Sudafed from pharmacy shelves doesn't work

- **Phenylephrine is everywhere and every nasal decongestant contains it**
- **The vote deeming it ineffective paves the way for it to be pulled from market**
- **READ MORE: FDA to reevaluate ineffective over-the-counter medicine**

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A medicine used by millions of Americans for a stuffy nose does not work, a Food and Drug Administration panel ruled today.

Phenylephrine is the most common active compound in over-the-counter drugs like Benadryl Allergy Plus Congestion, Sudafed PE, and Tylenol Cold and **Flu** Severe Day & Night.

But an **FDA** panel said after a two-day review that the oral decongestant **'is not effective'** at standard or even high doses compared to a placebo.

Their ruling is not binding but strongly suggests the agency could soon heed their advice and pull its approval, forcing companies to pull or reformulate their products.

The ingredient is protected under the FDA's Generally Recognized as Safe and Effective (GRASE) designation, but a reversal of its approval could mean manufacturers including Bayer and **Johnson and Johnson** might need to reformulate.

The ingredient phenylephrine is common on pharmacy shelves and has received a desigation from the FDA that it is generally recognized as safe. But losing that designation could mean big players in the OTC medicines field will pull their products from shelves or reformulate

Phenylephrine is everywhere, so much so that nearly every nasal decongestant on pharmacy shelves contains it.

Drugs that contain it generated almost $1.8 billion in sales last year, according to data presented Monday by FDA officials.

A unanimous vote by the 16-member Nonprescription Drug Advisory panel could issue a major blow to the industry.

Today's ruling only applies to oral formulations of phenylephrine.

If the agency decides to pull oral phenylephrine's GRASE designation, major manufacturers of drugs like Sudafed PE and Benadryl may be forced to reformulate them.

Phenylephrine was approved by the FDA in the 1970s to shrink the dilated blood vessels in the nose, relieving nasal and sinus congestion.

But since then, more research has come out questioning whether oral formulations of the medicine have any measurable benefit, given the way it's metabolized in the body.

The medicine is metabolized in the gut, allowing just a fraction to enter the bloodstream, which is how it reaches the nose.

In fact, briefing documents compiled by the FDA show that **less than a one percent** concentration of the drug is able to reach the nose after being broken down in the gut.

The documents detailed flaws in the trials for the ingredient in the 1960s and 1970s, citing small sample sizes and relied on techniques no longer used by the FDA to approve medications.

The unanimous ruling does not concern another popular deconestant, pseudoephedrine.

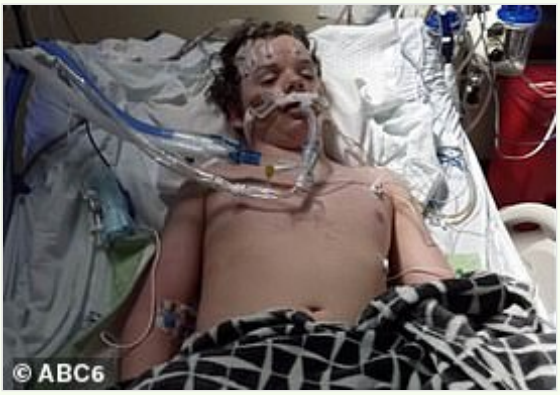
In 2006, a law passed to limit access to pseudoephedrine, the active ingredient in many versions of Sudafed by moving it behind pharmacy counters.

The ingredient is used to illegally process methamphetamine.

The original Sudafed that contains pseudoephedrine are less popular than versions that don't require a trip to the pharmacy counter, and American consumers largely prefer pills over nasal sprays.

Phenylephrine does seem to work better when applied directly to the nose.

READ MORE: Warning from health experts over deadly TikTok Benadryl challenge



The 'Benadryl Challenge' trend, which has already killed two US teens, sees people swallow multiple antihistamine tablets before posting videos of their experience.

In 2007, pharmacy professors at the University of Florida put forth a petition pressing the FDA to review whether a 10 milligram phenylephrine pill worked as a decongestant.

They said in a meta-analysis of available data: ‘Thus, the results of the studies reported after the 2007 Advisory Committee Meeting clearly demonstrate that [phenylephrine] is no more effective than placebo in decreasing nasal congestion and increasing the dose fourfold did not provide additional benefit.’

A series of studies pointing to its ineffectiveness have come out since then.

In 2015, a study sponsored in part by the New Jersey-based pharmaceutical company Merck & Co found that the the 10 milligram dose, as well as 20, 30, or 40 milligram doses were ‘not significantly better than placebo at relieving nasal congestion' in a sample of 539 adults.

Medicines that could be pulled from the market

- Colrex Compound
- Colrex
- Tylenol Cold and Flu Severe Day & Night
- Codral Cold and Flu + Cough Day and Night
- Alka-Seltzer Plus Severe Cold & Flu Formula Effervescent Tablets
- XL-3 Cold Medicine
- Robitussin Peak Cold Nighttime Nasal Relief
- Tylenol Sinus Congestion & Pain Nighttime
- Norel SR
- Trital SR
- Vicks Sinex
- Benadryl Allergy Plus Congestion
- Mucinex products
- Advil Allergy and Congestion Relief
- Vicks Nyquil Severe Cold and Flu