MARCO RUBIO
FLORIDA

United States Senate
WASHINGTON, DC 20510-0908

COMMITTEES:
APPROPRIATIONS
FOREIGN RELATIONS
SELECT COMMITTEE ON INTELLIGENCE
SMALL BUSINESS AND ENTREPRENEURSHIP
SPECIAL COMMITTEE ON AGING

September 28, 2023

Mr. Nicandro Durante
Chief Executive Officer
Reckitt Benckiser Group
103-105 Bath Road
Slough
Berkshire
SL1 3UH
United Kingdom

Dear Mr. Durante:

I write with regard to the U.S. Food and Drug Administration (FDA) Non-prescription Drug Advisory Committee's conclusion that current data does not show that orally administered phenylephrine, under the 10-milligram recommended dosage, is an effective nasal decongestant. Millions of Americans have relied on your phenylephrine-based products to achieve relief. It is concerning that despite a multitude of evidence proving the inefficacy of this ingredient, your company has deceived sick Americans in pursuit of low manufacturing costs and high profit margins.

Earlier this month, the FDA Non-prescription Drug Advisory Committee members unanimously agreed that current evidence proves that oral phenylephrine is not beneficial. As you know, the FDA initially designated the ingredient as "safe and effective" for over the counter (OTC) use in 1976, when the agency was approving drugs under much less stringent regulations. Over time, the FDA has revised its formal safety and efficacy standards, yet never re-evaluated this drug's efficacy with these updated standards. Hundreds of over the counter products containing oral phenylephrine are currently sold today.

However, as early as 2007, researchers petitioned the FDA to review the data and remove oral phenylephrine from the market due to research showing it did not outperform placebo pills in effectively addressing nasal decongestion. The initial studies used for approval contained numerous "methodological and statistical" flaws, used "extremely small" sample sizes, did not control for bias, and based their conclusions on research techniques no longer accepted by the FDA. Since 2016, three additional studies have found that oral phenylephrine is not effective when compared with a placebo.

Americans put their faith in pharmaceutical companies, and the FDA, to sell products that are both safe and effective in treating the symptoms listed on the packaging. It is concerning that the data proving phenylephrine's inefficacy has been present for so many years, yet companies have not adjusted their dosage or composition of their products. To provide clarity and transparency to the American people, I respectfully request that you provide answers to the following questions:

- What qualities of phenylephrine led your company to include it in your oral/nasal decongestant products?
- Was your company aware of the multiple challenges to FDA's approval and the associated studies that back these claims?
- If yes, why did your company agree to use phenylephrine in your oral/nasal decongestant products despite data proving it was ineffective?
- Given the FDA Nonprescription Drugs Advisory Committee's decision, does your company intend to continue using phenylephrine in your over the counter nasal decongestant products?
- If not, do you intend to replace phenylephrine with a different decongestant, such as pseudoephedrine?

As we enter another cold and flu season, it is important that Americans receive answers about the products they have long trusted for relief. Thank you for your attention to this matter and I look forward to your prompt response.

Sincerely,

Marco Rubio
U.S. Senator