ERRATUM to FDA Briefing Document

Efficacy of Oral Phenylephrine as a Nasal Decongestant

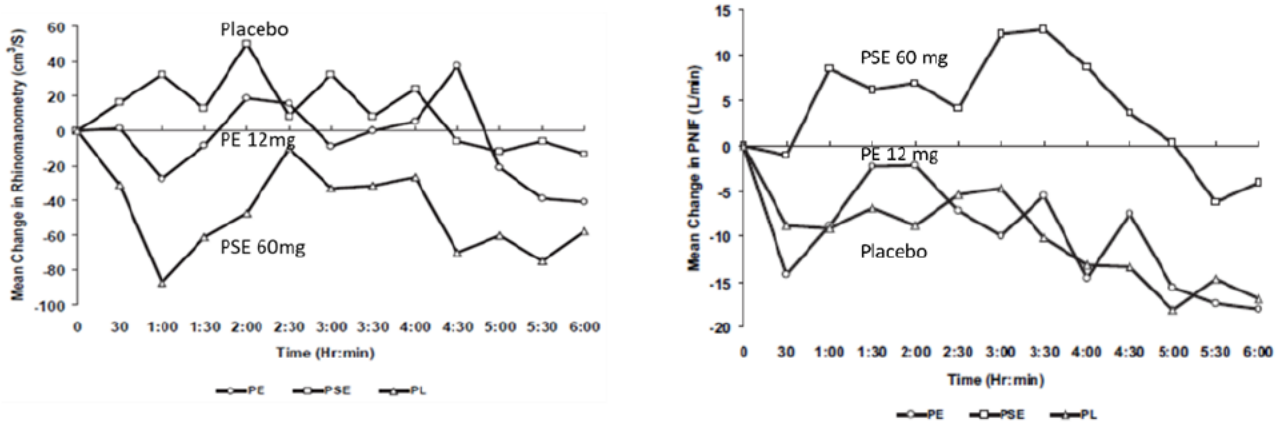
Nonprescription Drugs Advisory Committee Meeting
September 11 and 12, 2023

The briefing document has been redacted to remove information regarding issues not being discussed at this advisory committee meeting.

Section 3.3.1.1. Study P04579 *(Horak et al. 2009)*, Figure 13, page 39

The labeling of the pseudoephedrine and placebo treatment arms on the left-hand side (Nasal Rhinometry) of Figure 13 (page 39) of the Briefing Document are incorrectly designated as showing pseudoephedrine in place of placebo, and placebo in place of pseudoephedrine (the phenylephrine treatment arm is correctly labeled). The labeling of treatment arms in the right-hand figure (Peak Nasal Inspiratory Flow) is correct. The original and corrected figures are shown below, and the corrected treatment arm designations are shown in red font.

Original Figure 13. EEU Study P04579. Mean Change in Nasal Rhinometry (Left) and Peak Nasal Inspiratory Flow (Right) at 30-Minute Intervals After Drug Administration



Sources: Schering-Plough Merck 2007 NDAC Briefing Document[45] and Horak et al. (2009).
Abbreviations: EEU, environmental exposure units; NDAC, Nonprescription Drugs Advisory Committee; PE, phenylephrine; PSE, pseudoephedrine; PL, placebo

Corrected Figure 13. EEU Study P04579. Mean Change in Nasal Rhinometry (Left) and Peak Nasal Inspiratory Flow (Right) at 30-Minute Intervals After Drug Administration