

## AMENDMENT 1

### Reason for Change:

The expired carbon monoxide criterion used to screen participants prior to each test session will be changed from an exhaled CO level of  $\leq 10$  ppm to  $\leq 12$  ppm. This change is requested due to unanticipated expired CO levels of 11 ppm among 25% of participants tested for eligibility at Test Session 1. This change should provide the ability to include smokers who report having abstained from cigarette use for at least 12 hours without compromising their incoming serum nicotine levels.

### Update:

Throughout the protocol, the expired CO cutoff level participants must meet prior to each test session will be changed from  $\leq 10$  ppm to  $\leq 12$  ppm. The following protocol locations are affected:

- *Section 4 Study Design and Randomization* – page 6
- *Section 5.4 Selection of Participants* – pages 8-9
- *Section 6.4 Diet, Fluid, Tobacco, and Activity Restriction* – paragraph 1, page 12
- *Section 6.6 Test Session Eligibility* – page 13