Errata

On Sample Size Calculation in Bioequivalence Trials
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1. Equations for μ_T and μ_R on page 159 should be

$$\mu_T = E(X) = \exp(\mu_X^* + \sigma^2/2)$$

$$\mu_R = E(Y) = \exp(\mu_Y^* + \sigma^2/2)$$

$$\Rightarrow \log[\exp(\mu_X^* - \mu_Y^*)] = (\mu_X^* - \mu_Y^*)$$

2. The second part (following the $\approx$ symbol) of the second major expression on page 160 should have σ instead of $\hat{\sigma}$.

3. The second part of Eq. (1) on page 160 should be

$$n \geq \frac{2\sigma^2[t(\alpha, 2n-2) + t(\beta/2, 2n-2)]^2}{\Delta^2} \qquad \theta = 0$$

4. The first line below Eq. (1) should state $\theta \neq 0$ instead of $\varepsilon = 0$.

5. Eq. (2) on page 161 should be

$$n \geq \frac{\sigma_e^2[t(\alpha, 2n-2) + t(\beta, 2n-2)]^2}{(\Delta - |\theta|)^2} \qquad \theta \neq 0$$

$$n \geq \frac{\sigma_e^2[t(\alpha, 2n-2) + t(\beta/2, 2n-2)]^2}{\Delta^2} \qquad \theta = 0$$

6. Eqs. (3) and (4) (page 162) should, in each case, have an opening bracket ([) following σ^2. The second part of each equation should specify $\theta' = 0$ instead of $\theta' \neq 0$.

7. In Tables I and II (page 163) sample sizes were calculated using $|\theta'|$ values of 0, 0.5, 0.1, and 0.15. These values correspond to 0, 5.13, 10.52, and 16.18% differences between test and reference products on the raw data scale. According to the definition of $|\theta'| = |\log(\mu_T/\mu_R)|$ on page 162, $|\theta'|$ values of 0.04879, 0.09531, and 0.1398, corresponding to $\ln(1.05)$, $\ln(1.10)$, and $\ln(1.15)$ should have been used.

8. On page 165, under Bioavailability Limits, the value of $\log(1.25)$ is given as 0.2331. The correct value is 0.2231. The correct value was used in the calculation of Tables I and II.

9. In Appendix A, page 166, the expression for t^* should be

$$t^* = \frac{Y_T - Y_R - \theta}{\hat{\sigma}\sqrt{1/n_1 + 1/n_2}}$$

The text under this expression should state "... Under the assumption $n = n_1 = n_2 \ldots$"

10. Appendix A, page 167, the third major expression should be

$$P\left(t^* < \frac{\Delta - \theta}{\sigma\sqrt{2/n}} - t(\alpha, 2n - 2)\right)$$

11. The fourth major expression on page 167 should have σ instead of α in the denominator of the first term.

12. The line following the sixth major expression should state $\theta \neq 0$.

13. The second set of expressions in Appendix B (page 168) should be designated as (B2).