

**Errata to the FDA Briefing Document  
Peripheral and Central Nervous System Drugs Advisory Committee Meeting  
April 19, 2018**

1. Page 10, Table 2. The mean value for 20 mg/kg/day dose should be 3.2 and the mean value for the 10 mg/kg/day dose should be 3.0.

2. Page 15. The final sentence on the page should read:

Newly exposed subjects in the extension study included subjects who had been assigned to placebo in the initial trials and switched to open-label cannabidiol.

3. Page 17, Table 9. The variable of “weight (kg)” should be “BMI (kg/m<sup>2</sup>)”.

4. Page 18. The final sentence of the first paragraph should read:

Approximately 25% of subjects were taking valproate (without clobazam), 33% were taking clobazam (without valproate), 22% were taking both valproate and clobazam, and 22% were taking neither valproate or clobazam.

5. Page 23. The second sentence under “Transaminase elevations” should read:

In the three pivotal trials (1332B, 1414, and 1423), the incidence of elevation of ALT or AST >3X the upper limit of normal (ULN) was 2/219 (0.9%) in placebo, 2/67 (3.0%) in CBD 10 mg/kg/day, and 41/226 (18.1%) in CBD 20 mg/kg/day.

6. Page 60, Table 11:

- VAS Drug Liking for THC 10 mg: symbol should be ^ to indicate significance of p<0.0001
- VAS Overall Drug Liking for CBD 1500 mg: symbol should be removed to indicate no statistically significant difference from placebo
- VAS Good Drug Effects for CBD 4500 mg: symbol should be # to indicate significance of p<0.001
- VAS High for THC 30 mg: mean and standard deviation should be 71 ± 35
- VAS Alert/Drowsy for CBD 1500 mg: symbol should be \* to indicate significance of p<0.05