



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Translational Sciences  
Office of Biostatistics

## STATISTICAL REVIEW AND EVALUATION

### CLINICAL STUDIES - ADDENDUM

**NDA/BLA #:** NDA 205831

**Drug Name:** (b) (4) <sup>TM</sup> (Methylphenidate Hydrochloride Extended-Release Capsules) 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg (b) (4)

**Indication(s):** Attention Deficit Hyperactivity Disorder

**Applicant:** Rhodes Pharmaceuticals LP

**Date(s):** Submission data: June 18, 2014  
PDUFA due date: April 18, 2015

**Review Priority:** Standard

**Biometrics Division:** Division of Biometrics I

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**Keywords:** Clinical Study; NDA Review; ADHD.

## Statistical Review Addendum

This addendum corrects the Table 3 in the statistical NDA review of NDA 205831. This table comes from the sponsor's clinical study report (CSR). We noted the errors in the table and asked the sponsor to submit a corrected version. The sponsor could not submit it in time. The corrected table is attached below.

**Table 1: Demographics for Trial RP-BP-EF002**

Demographic Characteristic	10 mg Biphentin (N=49)	15 mg Biphentin (N=44)	20 mg Biphentin (N=45)	40 mg Biphentin (N=45)	Placebo (N=47)	All (N=230)
Mean±SD Age (yrs)	10.5±2.89	10.2±3.08	11.1±3.51	11.2±2.49	10.9±3.05	10.8±3.02
Age Group, No. (%)						
6-8 yrs	13 (26.5)	17 (38.6)	13 (28.9)	6 (13.3)	11 (23.4)	60 (26.1)
9-11 yrs	16 (32.7)	11 (25.0)	12 (26.7)	17 (37.8)	20 (42.6)	76 (33.0)
12-14 yrs	15 (30.6)	12 (27.3)	9 (20.0)	19 (42.2)	8 (17.0)	63 (27.4)
15-18 yrs	5 (10.2)	4 (9.1)	11 (24.4)	3 (6.7)	8 (17.0)	31 (13.5)
Sex, No. (%)						
Male	30 (61.2)	30 (68.2)	31 (68.9)	33 (73.3)	30 (63.8)	154 (67.0)
Female	19 (38.8)	14 (31.8)	14 (31.1)	12 (26.7)	17 (36.2)	76 (33.0)
Race, No. (%)						
White	34 (69.4)	26 (59.1)	33 (73.3)	32 (71.1)	33 (70.2)	158 (68.7)
Black	13 (26.5)	11 (25.0)	9 (20.0)	11 (24.4)	9 (19.1)	53 (23.0)
Asian	0	2 (4.5)	0	0	1 (2.1)	3 (1.3)
American Indian or Alaska Native	0	0	0	1 (2.2)	1 (2.1)	2 (0.9)
Native Hawaiian or Other Pacific Islander	0	2 (4.5)	0	0	0	2 (0.9)
Other	2 (4.1)	3 (6.8)	3 (6.7)	1 (2.2)	3 (6.4)	12 (5.2)
Ethnicity, No. (%)						
Hispanic or Latino	4 (8.2)	8 (18.2)	7 (15.6)	4 (8.9)	3 (6.4)	26 (11.3)
Not Hispanic or Latino	45 (91.8)	36 (81.8)	38 (84.4)	41 (91.1)	44 (93.6)	204 (88.7)
Weight (kg)						
Mean±SD	43.83±19.5	44.59±21.7	45.75±20.6	48.84±18.7	40.46±14.4	44.64±19.1
Min, Max	20.5, 102.5	16.8, 125.5	18.5, 95.5	27.0, 114.5	21.6, 81.8	16.8, 125.5

Source: Sponsor's Table 11-2 in CSR.

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/s/  
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