

Addendum to Statistical Review

NDA Number: 22-532 / Supporting Document 001
Drug Name: Beyaz (0.020 mg ethinylestradiol + 3.0 mg drospirenone + 0.451 mg levomefolate calcium)
Indication(s): Improvement in folate status in women who elect to use an oral contraceptive
Applicant: Bayer HealthCare Pharmaceuticals Inc.
Date(s): Letter Date: August 21, 2009 PDUFA Date: September 24, 2010
Review Priority: 1 Standard
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This addendum to the statistical review for this application corrects typographical errors in Table A.4 in the Appendix. The revised table is presented below with the affected values underlined.

Table A.4
Study A43598: Plasma Folate Levels (nmol/L) - Treatment Difference for Change from Baseline at Week 24
(Per Protocol Population, Using All Sites and Excluding Sites 104 and 108)

	n	Baseline	LS Mean ¹	LS Mean Difference ¹ (95% C.I.)	p-value
Using All Sites					
YAZ + Metafolin	196	<u>45.0</u>	16.0	18.9 (14.0, 23.7)	< 0.0001
YAZ	66	<u>43.1</u>	-2.9		
Excluding Sites 104 and 108					
YAZ + Metafolin	129	41.9	16.2	17.4 (11.5, 23.3)	< 0.0001
YAZ	47	41.2	-1.2		

Source: Statistical Reviewer's analysis and Table 140, page 766 of 870, and Table 152, page 782 of 870 of Study A43598 report.

¹ Least Squares mean estimates, confidence intervals, and p-values based on an ANCOVA model with treatment as factor and baseline value as covariate.

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