

Addendum to the Clinical Pharmacology Review Office of Clinical Pharmacology (OCP)

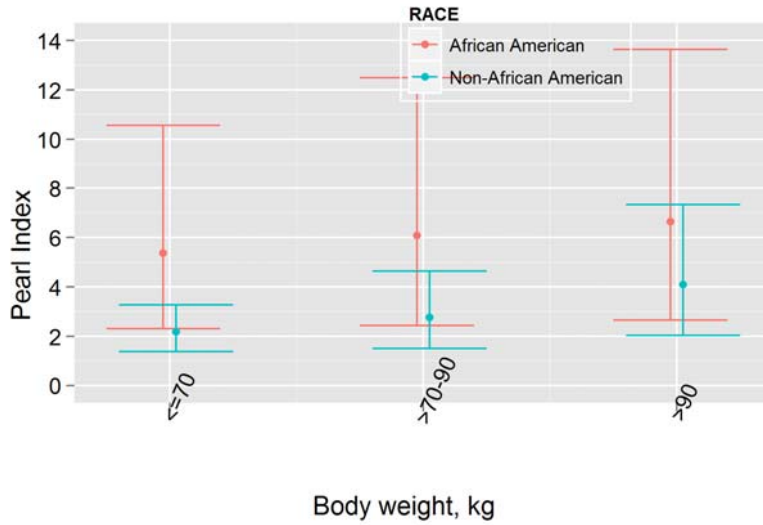
NDA: 204061	Date of Submission: May 31, 2012 (cover letter)
Generic Name:	Levonorgestrel (LNG)/ ethinyl estradiol (EE)
Proposed Brand Name:	Quartette™
Formulation:	Tablet
Strengths:	150 mcg/20 mcg, 150 mcg/25 mcg, and 0.15 mg/3 mcg LNG/EE, and 10 mcg EE
OCP Division:	Division of Clinical Pharmacology 3
Office of New Drugs (OND): Products	Division of Reproductive and Urologic
Route of Administration:	Oral
Indication:	Prevention of Pregnancy
Dosage and Administration:	QD for 91 days
Type of Submission:	Original NDA, 505b(2)
Sponsor:	Teva Pharmaceuticals Frazer, PA
Reviewer:	Sayed (Sam) Al Habet, R.Ph., Ph.D.
Secondary Reviewer:	Myong-Jin Kim, Pharm.D.
Pharmacometrics Reviewer:	Jeff Florian, Ph.D.
Pharmacometrics Secondary Reviewer:	Yaning Wang, Ph.D.

Subsequent to the finalization of the Clinical Pharmacology review for NDA 204061, a discrepancy was noted. The issue is discussed below.

An incorrect version of the figure on pg 18 and pg 73 of the Clinical Pharmacology Review was included. Corrected figures depicting Pearl Index for these subgroups is shown below. The conclusion associated with the original figures (e.g., the increase in Pearl Index for African Americans is not solely explained by body weight) remains unchanged.

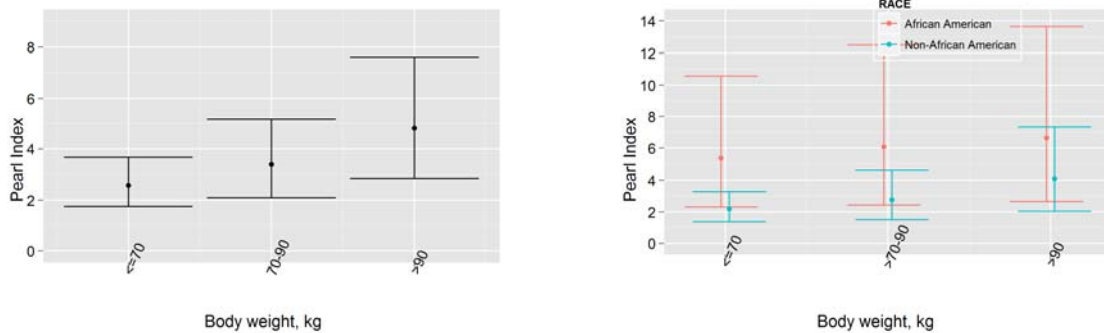
(pg. 18)

Figure 2.8 Pearl Index relative to Body Weight and Race (Study DR-103-301, see Appendix 4.3.1)



(pg 73)

Figure 1: Pearl Index from DR-103-301, for All Subjects or Grouped by Base into Three Body Weight Categories for a 28-day cycle equivalent



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/s/

JEFFRY FLORIAN
02/25/2013

YANING WANG
02/25/2013