

# Addendum to the Clinical Pharmacology Review

## Office of Clinical Pharmacology (OCP)

---

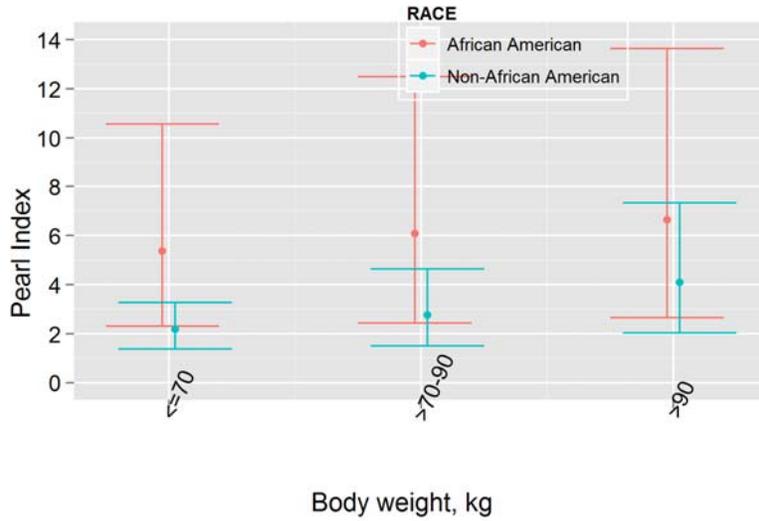
<b>NDA: 204061</b>	<b>Date of Submission:</b> May 31, 2012 (cover letter)
<b>Generic Name:</b>	Levonorgestrel (LNG)/ ethinyl estradiol (EE)
<b>Proposed Brand Name:</b>	Quartette™
<b>Formulation:</b>	Tablet
<b>Strengths:</b>	150 mcg/20 mcg, 150 mcg/25 mcg, and 0.15 mg/3 mcg LNG/EE, and 10 mcg EE
<b>OCP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

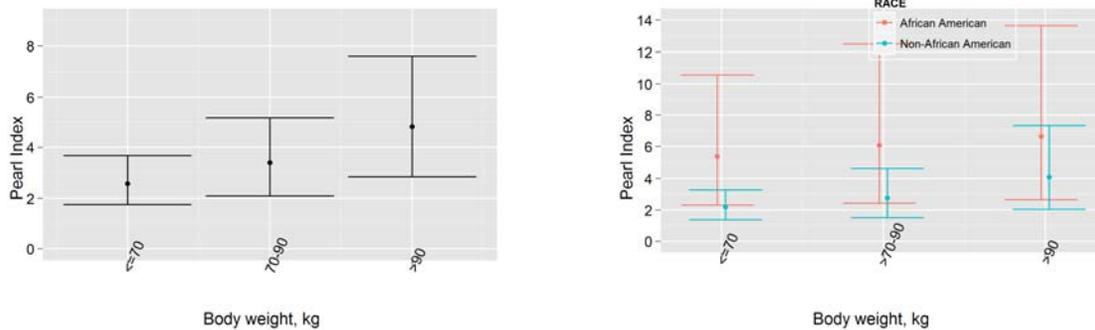
(pg. 18)

**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**



-----  
**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

JEFFRY FLORIAN  
02/25/2013

YANING WANG  
02/25/2013