

**ERRATA**  
**to the**  
**FDA Briefing Document**  
**Endocrinologic and Metabolic Drugs**  
**Advisory Committee Meeting**  
**May 19, 2011**

1. On Page 29 of 63: Clinical Briefing Document currently reads:

Measurement of Baseline albuminuria was not collected in the ACCORD-Lipid patients.

Change to: Measurement of Baseline albuminuria was not *reported* in the ACCORD-Lipid patients.

2. On Page 8 of 63: Clinical Briefing Document currently reads:

Trilipix<sup>®</sup> (fenofibric acid) belongs to the class of fenofibrate products; the non-proprietary name is choline fenofibrate. Trilipix<sup>®</sup> and other fenofibrates are "prodrugs" and therefore are pharmacologically inactive.

Change to:"Trilipix<sup>®</sup> (fenofibric acid) belongs to the class of fenofibrate products; the non-proprietary name is choline fenofibrate. Trilipix<sup>®</sup> *is fenofibric acid which is the active moiety of fenofibrate. Fenofibrate is a prodrug, which must be converted to the active moiety (fenofibric acid).*"

3. On Page 29 of 63: Clinical Briefing Document currently reads:

Table 12: Primary Outcome by TG/HDL Combinations

	<b>Fenofibrate + Simvastatin</b>	<b>Simvastatin Monotherapy</b>	<b>Hazard Ratio</b>	<b>95% CI</b>	<b>P value for Interaction</b>
<b>TG ≥ 204 mg/dL/ HDL-C ≤ 34 mg/dL</b>	60/485 (12.4%)	79/456 (17.3%)	0.692	(0.494, 0.969)	0.057
<b>All other patients</b>	226/2264 (10.1%)	228/2284 (10.1%)	0.992	(0.826, 1.192)	0.935

Change to:

Table 12: Primary Outcome by TG/HDL combinations

	<b>Fenofibrate + Simvastatin</b>	<b>Simvastatin Monotherapy</b>	<b>Hazard Ratio</b>	<b>95% CI</b>	<b>Nominal p-Value</b>	<b>P value for Interaction</b>
<b>TG ≥ 204 mg/dL/ HDL-C ≤ 34 mg/dL</b>	60/485 (12.4%)	79/456 (17.3%)	0.692	(0.494, 0.969)	0.032	0.057
<b>All other patients</b>	229/2264 (10.1%)	231/2284 (10.1%)	0.992	(0.826, 1.192)	0.935	

4. On Page 42 of 63: Clinical Briefing Document currently reads:

In comparison, the mean percent change from Baseline to Closeout in the Fenofibrate group for serum creatinine was 11%.

Change to:

"In comparison, the mean percent change from Baseline to Closeout in the ~~Fenofibrate~~ *Placebo* group for serum creatinine was 11%."

5. On Page 41 of 63: Clinical Briefing Document: Please note the strikethrough numbers are replaced by numbers in bold.

Table 21: Indicators of Chronic Kidney Disease Risk at Baseline

	<b>Fenofibrate N=2765</b>	<b>Placebo N=2753</b>
<b>eGFR (baseline)</b>		
30-49 mL/min/1.73 m <sup>2</sup>	70 (2.5%)	71 (2.6%)
>50 mL/min/1.73 m <sup>2</sup>	2679 (96.9%)	2668 (96.9%)
Missing	16 (0.6%)	14 (0.5%)
<b>Creatinine (baseline), mean, mg/dL, (SD)</b>	0.9 (0.2)	0.9 (0.2)
Missing	16 (0.6%)	14 (0.5%)
<b>On ACE-Inhibitor (baseline)</b>		
Yes	1473 (53.3%)	1494 (54.3%)
No	1292 (46.7%)	1259 (45.7%)
<b>On ARB (baseline)</b>		
Yes	405 (14.6%)	433 (15.7%)
No	2360 (85.4%)	2320 (84.3%)
<b>Duration of diabetes, years Mean (SD)</b>	10.7 (7.5)	10.7 (7.6)
Missing	<b>25</b> -46 (0.5%)	<b>18</b> -14 (0.5%)
<b>Glycated hemoglobin,</b>		

	<b>Fenofibrate N=2765</b>	<b>Placebo N=2753</b>
<b>percent</b> Mean (SD)	8.3 (1.0)	8.3 (1.0)
Missing	<b>6 7</b> (%)	3 (%)
<b>Systolic BP, mmHg</b> Mean (SD)	133.8 (17.7)	134.0 (17.9)
Missing	21	23
<b>Diastolic BP, mmHg</b> Mean (SD)	73.9 (10.7)	74.0 (10.8 <b>9</b> )
Missing	21	23

DMEP notes there are other minor typographical errors not of clinical importance:

**Clinical Briefing Document:**

**Page 31, Table 13.** Please note that in the 10X to 20X ULN row, placebo arm, the percentage should be 0.3% instead of 0.2%. This also applies to the last sentence prior to Table 13.

**Page 33, Table 14, Row 17, Patient 12011.** Serum creatinine value is 2.0 (instead of 1.9).

**Page 34, Table 16, 3<sup>rd</sup> Row.** This information appears to be for patient 12908 rather than 12098.

**Page 39, Table 19.** Please note that the year for the onset date for subject 14408 should be "2003" instead of "203."

**Page 52, Table 27.** Moderate dose statin column header says "N-491" instead of "N=491." Fenofibric Acid + Low-dose statin column, final row: Max LDL-C should be 324 (instead of 325).

**Page 53 & 54, Table 29.** Please note that in Table 29 in the last column on page 53 and page 54, "High-dose Stain" should be "High-dose Statin."

**Page 54, Table 29, Header Row.** Inconsistent hyphenation of P-value. Fenofibric Acid + Moderate-dose Statin, Non-HDL-C final mean row: Value should be 125.7 (instead of 125.6).

**Page 55, Table 30, Header Row, Fenofibric Acid Column.** Sample size should be 490 (instead of 49).