

MEMORANDUM

DATE: September 14, 2001

TO: Advisory Committee Members and Guests

FROM: Tenofovir Review Team

THROUGH: Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products

SUBJECT: **Errata for Background Package for NDA 21-356: VIREAD (tenofovir disoproxil fumarate)**

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Section: IV. Summary of Clinical Virology:

Table IVD: HIV RNA Response by Number of Baseline TAMs

# baseline TAMs	Mean DAVG ₂₄ (N)	
	Tenofovir	Placebo
No TAMs	-0.80 (68)	-0.11 (29)
Any TAMs	-0.50 (154)	0 (81)
1 –2 TAMs	-0.66 (55)	-0.4 (33) -0.04 (33)
3 TAMs	-0.44 (59)	+0.04 (29)
> 4 TAMs	-0.35 (40)	+0.03 (19)
≥ 3 TAMs + M41L or L210W	-0.21 (57)	+0.01 (29)
≥ 3 TAMs / No M41L or L210W	-0.67 (42)	+0.7 (19) +0.07 (19)

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Section: V. Safety Summary:

Subsection: f. Clinical Assessment of Bone Abnormalities: Incidence of Clinical Fractures

The mean time to fracture event was ~~311 days~~ 296 days.