

Food and Drug Administration

Bone, Reproductive and Urologic Drugs Advisory Committee Meeting

October 19, 2016

Errata to the FDA Briefing Materials

1. Section A, Page 1: The second sentence in the second to last paragraph should be changed from:
“The proposed starting dose is 0.75 mcg (one nasal spray) 30 minutes before bedtime, which can be increased, if needed, to 1.5 mcg (two nasal sprays) nightly,” to

“The proposed starting dose is 0.75 mcg thirty minutes before bedtime, which can be increased, if needed, to 1.5 mcg nightly.”
2. Section B, Page 1: The third sentence of the third paragraph should be changed from:

“The recommended starting dose is one intranasal spray (i.e. 0.75 mcg) in one nostril 30 minutes before bedtime, which may be increased to 1.5 mcg (i.e. 2 sprays) each night depending on the treatment response and tolerability,” to

“The recommended starting dose is 0.75 mcg thirty minutes before bedtime, which may be increased to 1.5 mcg each night depending on the treatment response and tolerability.”
3. Section B, Page 15, Table 6: The sample sizes for the nocturnal urine volume for the SER120 1.5 mcg dose and placebo under trial DB4 are missing. The numbers should be 229 for SER120 and 239 for placebo.
4. Section D. Page 13, Paragraph 3, third sentence should be changed from:

“Fasted serum sodium was assessed throughout the extension study at the following time points: Days 10, 15, 23, 29; and then at Weeks 8, 14, 22, 30, 38, 46, 54, 62, 70, 86, 94, 102, 110, 118, and 126,” to

“Fasted serum sodium was assessed throughout the extension study at the following time points: Days 10, 15, 23, 29; and then at Weeks 8 and 14 and every 8 weeks thereafter.”