

## Food and Drug Administration

### Bone, Reproductive and Urologic Drugs Advisory Committee Meeting

January 10, 2018

#### Errata to the FDA Briefing Materials

We have the following corrections and clarifications to the FDA briefing document for the January 10, 2018, Bone, Reproductive and Urologic Drugs Advisory Committee Meeting.

#### **Ex Vivo Conversion of Testosterone Undecanoate to Testosterone: Other Data on TU to Testosterone Conversion.**

On page 35 of the briefing document it states (bold-text added to identify the issue):

*1. Blood samples, collected in tubes **without an anticoagulant** and enzyme inhibitor, were spiked with TU (low: 500 ng/dL and high: 75,000 ng/dL), sat on ice for 60 min (labeled in **Tables 4 and 5** as 90 or 100 Minutes, respectively) or 120 min (labeled in **Tables 4 and 5** as 150 or 160 Minutes, respectively), incubated at room temperature for 30 min to clot, and centrifuged for 10 min at 2 to 8°C to obtain serum. One set of blood samples sat at room temperature for an additional 120 min, following 30 min at room temperature (to allow blood samples to clot), and was then centrifuged (150 or 160 Minutes). Changes in TU concentrations were compared to spiked blood samples that sat at room temperature for 30-40 min to permit clot formation and centrifuged to obtain serum (control). The TU mean percent differences from the control are presented below:*

*Two separate validation reports assessing TU stability by measuring the concentration of TU showed no apparent change in TU concentration, with some samples showing lower values while other showing higher values compared to the control (Tables 26 and 27).*

We have the following clarifications and corrections:

1. Blood samples were collected in tubes without an enzyme inhibitor but with anticoagulant, sodium heparin.
2. Samples were first allowed to sit at room temperature for 30 minutes to mimic clotting time (samples had anticoagulant).
3. After 30 minutes, samples were subjected to various processing conditions:
  - a. Control samples were processed immediately;
  - b. Experimental samples were evaluated with three processing conditions:
    - i. Samples left on ice for 60 minutes,
    - ii. Samples left on ice for 120 minutes,
    - iii. Samples left at room temperature for 120 minutes.

4. The final samples used in the analysis were plasma and not serum.
5. Tables 4 and 5 should be revised to Tables 26 and 27.