

Errata to the FDA Briefing Document

Pharmacy Compounding Advisory Committee

20-21 November 2017

1. Pages 5 -7. Substances Nominated for Inclusion on the 503A Bulks List (in order of discussion at the meeting). The order of discussion should read:

- A. L-citrulline
- B. Pregnenolone
- C. 7-Keto Dehydroepiandrosterone
- D. Astragalus extract 10:1
- E. Epigallocatechin Gallate
- F. Resveratrol

2. Pages 7 and 8. Draft Points to Consider, A. November 20, 2017 a.m. session should read:

FDA is proposing that L-citrulline for oral administration only be included on the 503A Bulks List. Should L-citrulline for oral administration only be placed on the list?

FDA is proposing that pregnenolone NOT be included on the 503A Bulks List. Should pregnenolone be placed on the list?

FDA is proposing that 7-keto dehydroepiandrosterone NOT be included on the 503A Bulks List. Should 7-keto dehydroepiandrosterone be placed on the list?

3. Page 8. Draft Points to Consider, B. November 20, 2017 p.m. session should read:

FDA is proposing that astragalus extract 10:1 NOT be included on the 503A Bulks List. Should astragalus extract 10:1 be placed on the list?

FDA is proposing that epigallocatechin gallate NOT be included on the 503A Bulks List. Should epigallocatechin gallate be placed on the list?

FDA is proposing that resveratrol NOT be included on the 503A Bulks List. Should resveratrol be placed on the list?