Errata to FDA Briefing Document
Pharmacy Compounding Advisory Committee (PCAC) Meeting
June 8, 2022

Note: Page numbers refer to pages in the substance specific FDA evaluation

FDA Errata to Ammonium Tetrathiomolybdate Briefing Document

Page numbers	
Section II.B. Clinical Trials Assessing Safety	
Page 11:	**First Paragraph, Second Sentence, "**Patients received ATTM for 8 weeks, with an average daily dose of 208 mg (range 120 mg to **360 mg**)…" Should read as, "Patients received ATTM for 8 weeks, with an average daily dose of 208 mg (range 120 mg to **410 mg**)…"
Page 11:	**Last Paragraph, Last Sentence , "**Four patients in the trientine group died during follow-up, 3 of whom had neurologic deterioration while receiving **trientine** t**herapy**…" Should read as, **"**Four patients in the trientine group died during follow-up, 3 of whom had neurologic deterioration while receiving **zinc maintenance**…"
Section II.C.2. Clinical Trials on Efficacy of Wilson Disease	
Page 21:	**Last Paragraph, Fourth Sentence, "**Patients received ATTM for 8 weeks at a mean daily dose of 208 mg (range 120 mg to **960 mg**)…" Should read as, "Patients received ATTM for 8 weeks at a mean daily dose of 208 mg (range 120 mg to **410 mg**)…"
Page 22:	**Last Paragraph, Second Sentence, "**A total of 23 patients received trientine HCl 1000 mg; 25 patients received ATTM **20 mg**/day." Should read as, **"**A total of 23 patients received trientine HCl 1000 mg; 25 patients received ATTM **120 mg**/day."

FDA Errata to Ferric Subsulfate Briefing Document

Page numbers	
Section II.C.1.a Use of ferric subsulfate during cervical biopsies	
Page 16:	**Last Paragraph, First Sentence**, **"**In a randomized, **placebo-**controlled trial (Hilal 2016), the application of Monsel's solution (ferric subsulfate) group (N=75) was compared to the control, "wait and see" group (N=70) who did not receive any hemostatic agent or other procedures which could lead to hemostasis (e.g., pressure on the biopsy site with a cotton swab) following colposcopic examination for cervical abnormalities and endocervical curettage.**"** Should read as, **"**In a randomized, controlled trial (Hilal 2016), the application of Monsel's solution (ferric subsulfate) group (N=75) was compared to the control, "wait and see" group (N=70) who did not receive any hemostatic agent or other procedures which could lead to hemostasis (e.g., pressure on the biopsy site with a cotton swab) following colposcopic examination for cervical abnormalities and endocervical curettage.**"**