

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***

June 8, 2022

**QUESTIONS**

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**Morning Session**

**Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances on the 503A Bulk List**

1. **VOTE:** FDA is proposing that enclomiphene citrate NOT be included on the 503A Bulks List. Should enclomiphene citrate be placed on the list?
  2. **VOTE:** FDA is proposing that glutathione NOT be included on the 503A Bulks List. Should glutathione be placed on the list?
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**Afternoon Session**

**Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances on the 503A Bulk List**

3. **VOTE:** FDA is proposing that ammonium tetrathiomolybdate NOT be included on the 503A Bulks List. Should ammonium tetrathiomolybdate be placed on the list?
4. **VOTE:** FDA is proposing that ferric subsulfate solid or powder NOT be included on the 503A Bulks List. Should ferric subsulfate solid or powder be placed on the list?

**Questions for PCAC Regarding Whether to Include Certain Entries on the Withdrawn and Removed List**

5. **VOTE:** FDA is proposing that “Lorcaserin hydrochloride: All drug products containing lorcaserin hydrochloride” be ADDED to the Withdrawn or Removed List under sections 503A and 503B of the FD&C Act. Do you agree?