

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting
June 8, 2022

DRAFT QUESTIONS

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?
-

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Questions for PCAC Regarding Whether to Include Certain Entries on the Withdrawn and Removed List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FDA is proposing that “Lorcaserin hydrochloride: All drug products containing lorcaserin hydrochloride” be ADDED to the Withdrawn or Removed List under sections 503A and 503B of the FD&C Act.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?