

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Pharmacy Compounding Advisory Committee (PCAC) Meeting

July 23-24, 2026

QUESTIONS

July 23, 2026, Morning Session

Questions for PCAC Regarding Whether FDA Should Include Certain Bulk Drug Substances on the 503A Bulks List

1. BPC-157-related bulk drug substances (BPC-157 (free base) and BPC-157 acetate)
 - a. **VOTE:** Should BPC-157 (free base) be placed on the list?
 - b. **VOTE:** Should BPC-157 acetate be placed on the list?
2. KPV-related bulk drug substances (KPV (free base) and KPV acetate)
 - a. **VOTE:** Should KPV (free base) be placed on the list?
 - b. **VOTE:** Should KPV acetate be placed on the list?

July 23, 2026, Afternoon Session

Questions for PCAC Regarding Whether FDA Should Include Certain Bulk Drug Substances on the 503A Bulks List

3. TB-500-related bulk drug substances (TB-500 (free base) and TB-500 acetate)
 - a. **VOTE:** Should TB-500 (free base) be placed on the list?
 - b. **VOTE:** Should TB-500 acetate be placed on the list?
4. MOTS-c-related bulk drug substances (MOTS-c (free base) and MOTS-c acetate)
 - a. **VOTE:** Should MOTS-c (free base) be placed on the list?
 - b. **VOTE:** Should MOTS-c acetate be placed on the list?

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DRAFT QUESTIONS (cont.)

July 24, 2026, Morning Session

Questions for PCAC Regarding Whether FDA Should Include Certain Bulk Drug Substances on the 503A Bulks List

5. Emideltide-related bulk drug substances (Emideltide (free base) and Emideltide acetate)
 - a. **VOTE:** Should Emideltide (free base) be placed on the list?
 - b. **VOTE:** Should Emideltide acetate be placed on the list?
6. Epitalon-related bulk drug substances (Epitalon (free base) and Epitalon acetate)
 - a. **VOTE:** Should Epitalon (free base) be placed on the list?
 - b. **VOTE:** Should Epitalon acetate be placed on the list?

July 24, 2026, Afternoon Session

Questions for PCAC Regarding Whether FDA Should Include Certain Bulk Drug Substances on the 503A Bulks List

7. Semax-related bulk drug substances (Semax (free base) and Semax acetate)
 - a. **VOTE:** Should Semax (free base) be placed on the list?
 - b. **VOTE:** Should Semax acetate be placed on the list?