

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
June 9, 2021

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 melatonin for oral administration be INCLUDED on the 503A Bulks List. Should melatonin for oral administration be placed on the list?
 2. **VOTE:** FDA is proposing that methylcobalamin NOT be included on the 503A Bulks List. Should methylcobalamin 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 choline chloride NOT be included on the 503A Bulks List. Should choline chloride be placed on the list?
4. **VOTE:** FDA is proposing that oxitriptan for oral administration be INCLUDED on the 503A Bulks List. Should oxitriptan for oral administration be placed on the list?

Question for PCAC Regarding Whether to Include an Entry on the Withdrawn and Removed List

5. **VOTE:** FDA is proposing that “Neomycin sulfate: All parenteral drug products containing neomycin sulfate (except when used for ophthalmic or otic use or in combination with polymyxin B sulfate for irrigation of the intact bladder)” be ADDED to the Withdrawn or Removed List under sections 503A and 503B of the FD&C Act. Do you agree?