

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
October 29, 2024

DRAFT QUESTIONS

Morning Session

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

1. **VOTE:** FDA is proposing that L-theanine NOT be included on the 503A Bulks List. Should L-theanine be placed on the list?
 2. **VOTE:** FDA is proposing that Ibutamoren mesylate NOT be included on the 503A Bulks List. Should Ibutamoren mesylate be placed on the list?
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Afternoon Session

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

3. **VOTE:** Do committee members agree to vote on Ipamorelin-related bulk drug substances discussed today (Ipamorelin (free base) and Ipamorelin acetate) as a group (Yes or No)? If any member of the Committee votes no, FDA will take individual votes on each of these substances.

If yes:

- a. **VOTE:** FDA is proposing that Ipamorelin (free base) and Ipamorelin acetate NOT be included on the 503A Bulks List. Should Ipamorelin (free base) and Ipamorelin acetate be placed on the list?

If no:

- b. **VOTE:** FDA is proposing that Ipamorelin (free base) NOT be included on the 503A Bulks List. Should Ipamorelin (free base) be placed on the list?
- c. **VOTE:** FDA is proposing that Ipamorelin acetate NOT be included on the 503A Bulks List. Should Ipamorelin acetate be placed on the list?

4. **VOTE:** FDA is proposing that Kisspeptin-10 NOT be included on the 503A Bulks List. Should Kisspeptin-10 be placed on the list?

Questions for PCAC Regarding Whether FDA should Include Certain Entries on the Withdrawn and Removed List

5. **VOTE:** FDA is proposing that “Hydroxyprogesterone caproate: All drug products containing hydroxyprogesterone caproate to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth” be ADDED to the Withdrawn or Removed List under sections 503A and 503B of the FD&C Act. Should this entry be placed on the list?