

**FOOD AND DRUG ADMINISTRATION (FDA)**

Center for Drug Evaluation and Research (CDER)

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

December 4, 2024

**QUESTIONS**

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**Morning Session**

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

1. **VOTE:** Do committee members agree to use a single vote to address the group of CJC-1295-related bulk drug substances discussed today (CJC-1295 (free base), CJC-1295 acetate, CJC-1295 with drug affinity complex (DAC) (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

If yes:

- a. **VOTE:** FDA is proposing that CJC-1295 (free base), CJC-1295 acetate, CJC-1295 DAC (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate NOT be included on the 503A Bulks List. Should CJC-1295 (free base), CJC-1295 acetate, CJC-1295 DAC (free base), CJC-1295 DAC acetate, and CJC-1295 DAC trifluoroacetate be placed on the list?

If no:

- b. **VOTE:** FDA is proposing that CJC-1295 (free base) NOT be included on the 503A Bulks List. Should CJC-1295 (free base) be placed on the list?
- c. **VOTE:** FDA is proposing that CJC-1295 acetate NOT be included on the 503A Bulks List. Should CJC-1295 acetate be placed on the list?
- d. **VOTE:** FDA is proposing that CJC-1295 DAC (free base) NOT be included on the 503A Bulks List. Should CJC-1295 DAC (free base) be placed on the list?
- e. **VOTE:** FDA is proposing that CJC-1295 DAC acetate NOT be included on the 503A Bulks List. Should CJC-1295 DAC acetate be placed on the list?
- f. **VOTE:** FDA is proposing that CJC-1295 DAC trifluoroacetate NOT be included on the 503A Bulks List. Should CJC-1295 DAC trifluoroacetate be placed on the list?
2. **VOTE:** Do committee members agree to use a single vote to address the group of AOD-9604-related bulk drug substances discussed today (AOD-9604 (free base) and AOD-9604 acetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

If yes:

- a. **VOTE:** FDA is proposing that AOD-9604 (free base) and AOD-9604 acetate NOT be included on the 503A Bulks List. Should AOD-9604 (free base) and AOD-9604 acetate be placed on the list?

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**QUESTIONS (cont.)**

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**Morning Session (cont.)**

If no:

- b. **VOTE:** FDA is proposing that AOD-9604 (free base) NOT be included on the 503A Bulks List. Should AOD-9604 (free base) be placed on the list?
  - c. **VOTE:** FDA is proposing that AOD-9604 acetate NOT be included on the 503A Bulks List. Should AOD-9604 acetate 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 use a single vote to address the group of Thymosin alpha-1-related bulk drug substances discussed today (Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate) (Yes or No)? If any member of the Committee votes no, FDA will take separate votes on each of these substances.

If yes:

- a. **VOTE:** FDA is proposing that Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate NOT be included on the 503A Bulks List. Should Thymosin alpha-1 (free base) and Thymosin alpha-1 acetate be placed on the list?

If no:

- b. **VOTE:** FDA is proposing that thymosin alpha-1 (free base) NOT be included on the 503A Bulks List. Should thymosin alpha-1 (free base) be placed on the list?
- c. **VOTE:** FDA is proposing that thymosin alpha-1 acetate NOT be included on the 503A Bulks List. Should thymosin alpha-1 acetate be placed on the list?