

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

***Pharmacy Compounding Advisory Committee (PCAC) Meeting***  
March 8-9, 2016

**DRAFT QUESTIONS**

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**March 8, 2016, a.m. session**

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

**VOTE: YES, NO, or ABSTAIN for each question**

1. FDA is proposing that quinacrine hydrochloride NOT be placed on the list of bulk drug substances that can be used in pharmacy compounding in accordance with section 503A of the FD&C Act (“the 503A bulk list”). Should quinacrine hydrochloride be placed on the list?
2. FDA is proposing that boswellia NOT be placed on the 503A bulk list. Should boswellia be placed on the list?

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**March 8, 2016, p.m. session**

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

**VOTE: YES, NO, or ABSTAIN for each question**

1. FDA is proposing that Aloe Vera freeze dried 200:1 NOT be placed on the 503A bulk list. Should Aloe Vera freeze dried 200:1 be placed on the list?
2. FDA is proposing that D-ribose NOT be placed on the 503A bulk list. Should D-ribose be placed on the list?
3. FDA is proposing that chondroitin sulfate NOT be placed on the 503A bulk list. Should chondroitin sulfate be placed on the list?
4. FDA is proposing that acetyl-L-carnitine NOT be placed on the 503A bulk list. Should acetyl-L-carnitine be placed on the list?

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**March 9, 2016**

**Questions for PCAC Regarding Whether to Include Two Categories of Drug Products on the Demonstrable Difficult to Compound List**

**VOTE: YES, NO, or ABSTAIN for each question**

1. FDA is proposing that metered dose inhalers be placed on the list of drug products that present demonstrable difficulties for compounding in accordance with sections 503A and 503B of the FD&C Act (“the difficult to compound list”). Should metered dose inhalers be placed on the list?
2. FDA is proposing that dry powder inhalers be placed on the difficult to compound list. Should dry powder inhalers be placed on the list?