

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

Pharmacy Compounding Advisory Committee (PCAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 23, 2016

DRAFT QUESTIONS

Morning Session

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

1. **VOTE:** FDA is proposing that chrysin 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 chrysin be placed on the list?
 2. **VOTE:** FDA is proposing that cesium chloride NOT be placed on the 503A bulk list. Should cesium chloride be placed on the list?
 3. **VOTE:** FDA is proposing that sodium dichloroacetate NOT be placed on the 503A bulk list. Should sodium dichloroacetate be placed on the list?
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Afternoon Session

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

1. **VOTE:** FDA is proposing that pyruvic acid for topical use be INCLUDED on the 503A bulk list. Should pyruvic acid for topical use be placed on the list?
2. **VOTE:** FDA is proposing that tea tree oil NOT be placed on the 503A bulk list. Should tea tree oil be placed on the list?
3. **VOTE:** FDA is proposing that 2,3-dimercapto-1-propanesulfonic acid (DMPS) NOT be placed on the 503A bulk list. Should DMPS be placed on the list?