

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

September 12, 2018

DRAFT QUESTIONS

Morning Session

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

1. **VOTE:** FDA is proposing that alpha lipoic acid solid oral dosage forms be INCLUDED on the 503A Bulks List. Should alpha lipoic acid solid oral dosage forms be placed on the list?
 2. **VOTE:** FDA is proposing that coenzyme Q₁₀ (ubiquinone) for oral administration be INCLUDED on the 503A Bulks List. Should coenzyme Q₁₀ (ubiquinone) for oral administration 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 Bulks List

3. **VOTE:** FDA is proposing that creatine monohydrate solid oral dosage forms be INCLUDED on the 503A Bulks List. Should creatine monohydrate solid oral dosage forms be placed on the list?
4. **VOTE:** FDA is proposing that pyridoxal 5 phosphate monohydrate (intravenous and oral dosage forms) be INCLUDED on the 503A Bulks List. Should pyridoxal 5 phosphate monohydrate (intravenous and oral dosage forms) be placed on the list?
5. **VOTE:** FDA is proposing that quercetin dihydrate NOT be included on the 503A Bulks List. Should quercetin dihydrate be placed on the list?