

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

November 3, 2016

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 glycolic acid, up to 70%, for topical use be INCLUDED on the 503A Bulks List. Should glycolic acid be placed on the list?
 2. **VOTE:** FDA is proposing that trichloroacetic acid for topical use be INCLUDED on the 503A Bulks List. Should trichloroacetic acid be placed on the list?
 3. **VOTE:** FDA is proposing that kojic acid NOT be included on the 503A Bulks List. Should kojic acid 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

1. **VOTE:** FDA is proposing that diindolylmethane NOT be included on the 503A Bulks List. Should diindolylmethane be placed on the list?
2. **VOTE:** FDA is proposing that vasoactive intestinal peptide NOT be included on the 503A Bulks List. Should vasoactive intestinal peptide be placed on the list?

Question for PCAC Regarding Whether to Include Certain Drug Products or Categories of Drug Products on the Difficult to Compound List

3. **VOTE:** FDA is proposing that drug products that employ transdermal or topical delivery systems be INCLUDED on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Should drug products that employ transdermal or topical delivery systems be placed on the list?