

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
May 8-9, 2017

DRAFT QUESTIONS

May 8, 2017, 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 nicotinamide adenine dinucleotide NOT be included on the 503A Bulks List. Should nicotinamide adenine dinucleotide be placed on the list?
 2. FDA is proposing that nicotinamide adenine dinucleotide disodium reduced NOT be included on the 503A Bulks List. Should nicotinamide adenine dinucleotide disodium reduced be placed on the list?
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May 8, 2017, 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 nettle NOT be included on the 503A Bulks List. Should nettle be placed on the list?
 2. FDA is proposing that ubiquinol NOT be included on the 503A Bulks List. Should ubiquinol be placed on the list?
 3. FDA is proposing that vanadyl sulfate NOT be included on the 503A Bulks List. Should vanadyl sulfate be placed on the list?
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May 9, 2017, a.m. session

Question 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 artemisinin NOT be included on the 503A Bulks List. Should artemisinin be placed on the list?

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DRAFT QUESTIONS (cont.)

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

VOTE: YES, NO, or ABSTAIN for each question

1. FDA is proposing that oral solid modified release drug products that employ coated systems be INCLUDED on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Should oral solid modified release drug products that employ coated systems be placed on the list?

DRAFT