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 20 – 21, 2017

QUESTIONS

November 20, 2017, a.m. session
Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances on the 503A Bulks List

VOTE: YES, NO, or ABSTAIN

1. FDA is proposing that L-citrulline for oral administration only be included on the 503A Bulks List. Should L-citrulline for oral administration only be placed on the list?

2. FDA is proposing that pregnenolone NOT be included on the 503A Bulks List. Should pregnenolone be placed on the list?

3. FDA is proposing that 7-keto dehydroepiandrosterone NOT be included on the 503A Bulks List. Should 7-keto dehydroepiandrosterone be placed on the list?

November 20, 2017, p.m. session
Questions for PCAC Regarding Whether to Include Certain Bulk Drug Substances on the 503A Bulks List

VOTE: YES, NO, or ABSTAIN

1. FDA is proposing that astragalus extract 10:1 NOT be included on the 503A Bulks List. Should astragalus extract 10:1 be placed on the list?

2. FDA is proposing that epigallocatechin gallate NOT be included on the 503A Bulks List. Should epigallocatechin gallate be placed on the list?

3. FDA is proposing that resveratrol NOT be included on the 503A Bulks List. Should resveratrol be placed on the list?

QUESTIONS (cont.)

November 21, 2017
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 liposome drug products be INCLUDED on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Should liposome drug products be placed on the list?

2. FDA is proposing that drug products produced using hot melt extrusion be INCLUDED on the Difficult to Compound List under sections 503A and 503B of the FD&C Act. Should drug products produced using hot melt extrusion be placed on the list?