February 23, 2015

Voting Questions for PCAC Regarding Whether to Include Certain Drugs on the Withdrawn or Removed List, and How to Describe Certain Entries

VOTE: YES, NO, or ABSTAIN for each question

1. FDA is proposing that “Alatrofloxacin mesylate: All drug products containing alatrofloxacin mesylate” be added to the Withdrawn or Removed List. Do you agree?

2. FDA is proposing that “Aminopyrine: All drug products containing aminopyrine” be added to the Withdrawn or Removed List. Do you agree?

3. FDA is proposing that “Astemizole: All drug products containing astemizole” be added to the Withdrawn or Removed List. Do you agree?

4. FDA is proposing that the current listing of “Bromfenac sodium: All drug products containing bromfenac sodium” on the Withdrawn or Removed List be modified to “Bromfenac sodium: All drug products containing bromfenac sodium (except ophthalmic solutions).” Do you agree?

5. FDA is proposing that “Cerivastatin sodium: All drug products containing cerivastatin sodium” be added to the Withdrawn or Removed List. Do you agree?

6. FDA is proposing that “Cisapride: All drug products containing cisapride” be added to the Withdrawn or Removed List. Do you agree?

7. FDA is proposing that “Esmolol hydrochloride: All parenteral drug products containing esmolol HCl that supply 250 mg/milliliter (mL) of concentrated esmolol per 10-mL ampule” be added to the Withdrawn or Removed List. Do you agree?

8. FDA is proposing that “Etretinate: All drug products containing etretinate” be added to the Withdrawn or Removed List. Do you agree?

9. FDA is proposing that “Gatifloxacin: All drug products containing gatifloxacin (except ophthalmic solutions)” be added to the Withdrawn or Removed List. Do you agree?

10. FDA is proposing that “Grepafloxacin: All drug products containing grepafloxacin” be added to the Withdrawn or Removed List. Do you agree?

11. FDA is proposing that “Methoxyflurane: All drug products containing methoxyflurane” be added to the Withdrawn or Removed List. Do you agree?

12. FDA is proposing that “Novobiocin sodium: All drug products containing novobiocin sodium” be added to the Withdrawn or Removed List. Do you agree?

13. FDA is proposing that “Oxycodone hydrochloride: All extended-release drug products containing oxycodone hydrochloride that have not been determined by FDA to have abuse-deterrent properties” be added to the Withdrawn or Removed List. Do you agree?

14. FDA is proposing that “Pemoline: All drug products containing pemoline” be added to the Withdrawn or Removed List. Do you agree?
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VOTE: YES, NO, or ABSTAIN for each question

15. FDA is proposing that “Pergolide mesylate: All drug products containing pergolide mesylate” be added to the Withdrawn or Removed List. Do you agree?

16. FDA is proposing that “Phenylpropanolamine (PPA): All drug products containing PPA be added to the Withdrawn or Removed List. Do you agree?

17. FDA is proposing that “Polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl: All drug products containing PEG 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution, and 10 mg or more of bisacodyl delayed-release tablet” be added to the Withdrawn or Removed List. Do you agree?

18. FDA is proposing that “Propoxyphene: All drug products containing propoxyphene” be added to the Withdrawn or Removed List. Do you agree?

19. FDA is proposing that “Rapacuronium bromide: All drug products containing rapacuronium bromide” be added to the Withdrawn or Removed List. Do you agree?

20. FDA is proposing that “Rofecoxib: All drug products containing rofecoxib” be added to the Withdrawn or Removed List. Do you agree?

21. FDA is proposing that “Sibutramine hydrochloride: All drug products containing sibutramine hydrochloride” be added to the Withdrawn or Removed List.

22. FDA is proposing that “Tegaserod maleate: All drug products containing tegaserod maleate” be added to the Withdrawn or Removed List. Do you agree?

23. FDA is proposing that “Troglitazone: All drug products containing troglitazone” be added to the Withdrawn or Removed List. Do you agree?

24. FDA is proposing that “Trovafloxacin mesylate: All drug products containing trovafloxacin mesylate” be added to the Withdrawn or Removed List. Do you agree?

25. FDA is proposing that “Valdecoxib: All drug products containing valdecoxib” be added to the Withdrawn or Removed List. Do you agree?

26. FDA is now proposing that the current entry of “Adenosine phosphate: All drug products containing adenosine phosphate” on the list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective, codified at 21 CFR 216.24 be updated to state “All drug products containing adenosine 5'-monophosphate (AMP), adenosine 5'-diphosphate (ADP), and adenosine 5'-triphosphate (ATP).” Do you agree?

27. FDA is proposing that “Chloramphenicol: All oral drug products containing chloramphenicol” be added to the Withdrawn or Removed List. Do you agree?
February 23, 2015

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 thymol iodide 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 thymol iodide be placed on the list?

2. FDA is proposing that silver protein mild NOT be placed on the 503A bulk list. Should silver protein mild be placed on the list?

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VOTE: YES, NO, or ABSTAIN for each question

3. FDA is proposing that squaric acid dibutyl ester be placed on the 503A bulk list. Should squaric acid dibutyl ester be placed on the list?

4. FDA is proposing that diphenylcyclopropenone be placed on the 503A bulk list. Should diphenylcyclopropenone be placed on the list?

5. FDA is proposing that cantharidin be placed on the 503A bulk list. Should cantharadin be placed on the list?

6. FDA is proposing that piracetam NOT be placed on the 503A bulk list. Should piracetam be placed on the list?