

Pprevnar? Pneumococcal 7-valent (4, 6B, 9V, 14, 18C, 19F, 23F) Conjugate Vaccine (Diphtheria CRM₁₉₇ Protein)

November 5, 1999

Questions to the Committee

- 1. Do the data provide sufficient evidence of efficacy against invasive disease for Pprevnar, as it was studied in the efficacy trial (i.e., after administration at 2, 4, 6, and 12-15 months of age)?**

If not, what additional information should be requested?

- 2. Do the data provide sufficient evidence of safety for Pprevnar?**

If not, what additional information should be requested?

- 3. Please discuss the data regarding concurrent use of Pprevnar with other vaccines administered according to the recommended schedule of infant and childhood immunizations.**

- 4. Please identify any issues that should be addressed by post-marketing studies.**