

Draft Discussion Points

The actual use study (AUS) was conducted in five family planning clinic settings across five states and five pharmacy stores in the state of Washington. A total of 585 subjects ages 14-44 years were enrolled from family planning clinics (94%) and pharmacy stores (6%) in the United States. Subjects were only allowed to purchase one package of Plan B, but were allowed additional purchases after undergoing a re-enrollment process. The duration of the study was 4 weeks.

1. Does the AUS demonstrate that consumers used the product as recommended in the proposed labeling?
2. Are the data from the AUS generalizable to the overall population of potential non-prescription users of Plan B?
3. Based on the data from the AUS and the review of the literature, is there evidence that non-prescription availability of Plan B leads to substitution of emergency contraception for the regular use of other contraceptive methods?
4. Do the data presented in the NDA demonstrate that Plan B is safe for use in the non-prescription setting?
5. Are the sponsor's plans for introduction of Plan B into the non-prescription marketplace adequate with respect to consumer access and safe use? In answering this question, you may consider other distribution mechanisms such as non-prescription restricted distribution.
6. Based on the data presented in the NDA, do you recommend that Plan B be switched from prescription to non-prescription status?
 - a) If yes, are there any additions or modifications you would recommend with regard to the proposed labeling and distribution plan?
 - b) If no, what additional information would be required?