

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

***Nonprescription Drugs Advisory Committee (NDAC) and the
Obstetrics, Reproductive, and Urologic Drugs Advisory Committee (ORUDAC)***
May 9-10, 2023

DRAFT QUESTIONS

1. **DISCUSSION:** Discuss whether consumers are likely to use norgestrel tablet in a safe and effective manner, considering the possibility of unintended pregnancy with incorrect use.

Specifically, discuss whether consumers are likely to adhere to taking the tablet daily at the same time of day, based solely upon the nonprescription labeling without any assistance from a healthcare professional.

Please discuss for the following consumer populations:

- a. General population of females of reproductive potential
b. Adolescents
c. Those with limited literacy
d. Those using concomitant products (e.g., anticonvulsant drugs) that may interact with and reduce efficacy of norgestrel tablet
2. **DISCUSSION:** The ACCESS Study- Use Phase had improbable dosing in approximately 1/3 of participants. If FDA were to recommend the Applicant conduct another Actual Use Study (AUS), what changes to the AUS design would the committee recommend? Consider the following:
 - a. e-diary design
b. e-diary recall period
c. Participant compensation structure
d. Methods ensuring e-diary data entry instructions are adequately comprehended
e. Incorporating a pathway allowing participants to ask a healthcare provider (HCP) before deciding study drug purchase
f. Study questions to determine timing of when participants spoke to a HCP during the study
3. **DISCUSSION:** Discuss whether there is sufficient information to conclude consumers in the following scenarios will appropriately deselect from norgestrel use:
 - a. Consumers with a history of or current diagnosis of breast cancer
b. Consumers with abnormal vaginal bleeding of undiagnosed etiology
c. Consumers who are using other hormonal contraceptives
4. **VOTE:** Is there adequate information to conclude that consumers will be likely to use norgestrel tablet properly, such that the benefits of making this available for nonprescription use (access without needing to interact with a healthcare professional), exceed the risks (such as inadequate adherence leading to contraceptive failure with unintended pregnancy, use of the medication by consumers with a contraindication to its use, failure to see a health care professional when appropriate)?
 - a. If you voted 'No', explain why you believe the risks outweigh the benefits for nonprescription use, and what additional data would be necessary to support approval.
 - b. If you voted 'Yes', explain why you believe the benefits outweigh the risks for nonprescription use.