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In Major Step For Women's Health, FDA Approves First Over-the-Counter Birth Control Pill

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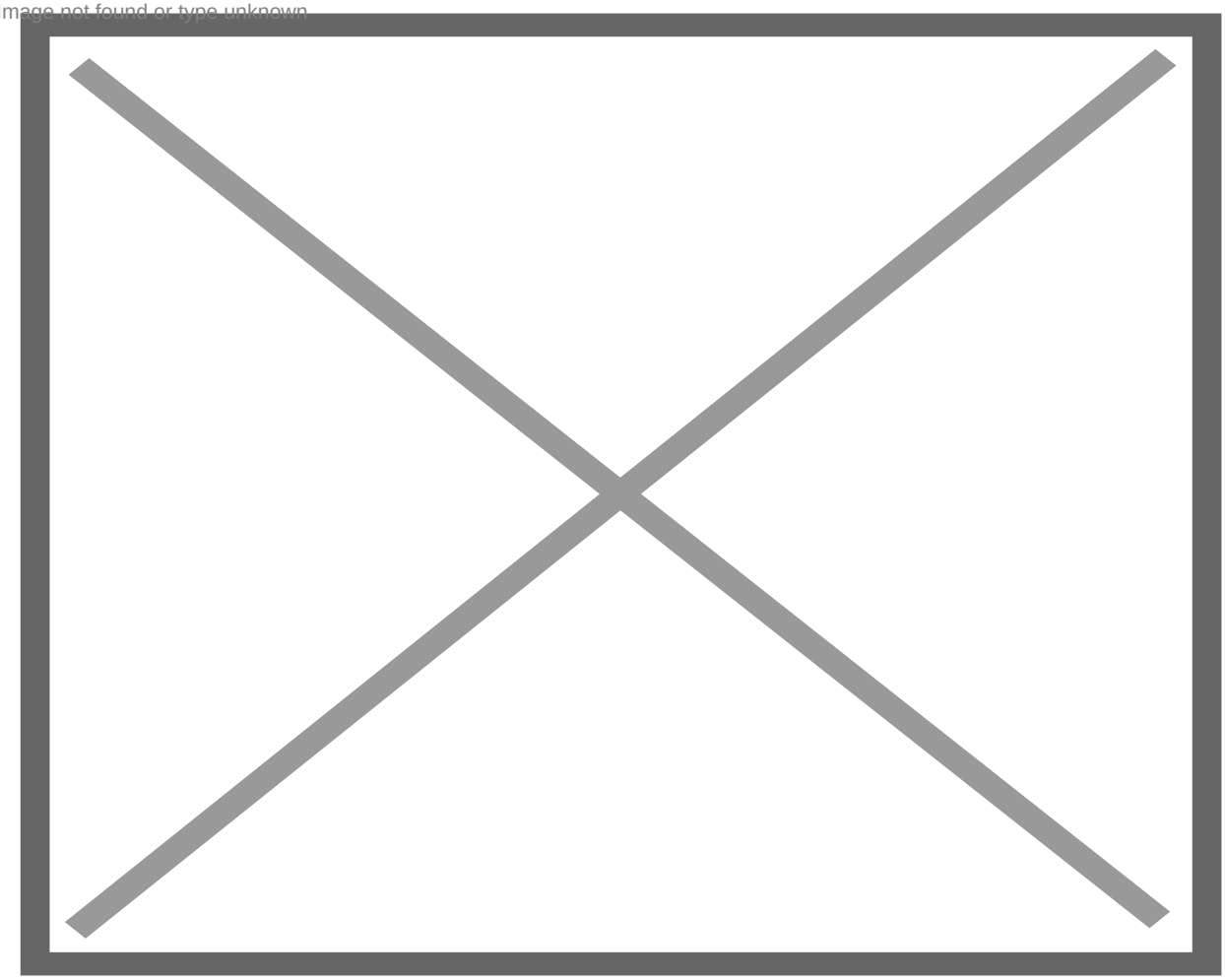

In a historic move, the U.S. Food and Drug Administration has granted approval for the first over-the-counter birth control pill in the United States. The FDA announced on Thursday that Opill (norgestrel), a daily oral contraceptive, can now be purchased without a prescription.

Opill offers a new level of accessibility for consumers who can now buy the oral contraceptive in drug stores, convenience stores, grocery stores, and online. The timeline and pricing of this nonprescription product will be determined by the manufacturer. Other approved formulations and dosages of oral contraceptives will continue to be available by prescription only.

"Today’s approval marks the first time a nonprescription daily oral contraceptive will be an available option for millions of people in the United States," said Patrizia Cavazzoni, M.D.,

director of the FDA’s Center for Drug Evaluation and Research. "When used as directed, daily oral contraception is safe and is expected to be more effective than currently available nonprescription contraceptive methods in preventing unintended pregnancy.”

The FDA said it hopes that the nonprescription availability of Opill will reduce barriers to access, allowing individuals to obtain an oral contraceptive without needing to see a healthcare provider first. This move is particularly significant considering almost half of the 6.1 million pregnancies in the U.S. each year are unintended. Unintended pregnancies can lead to negative maternal and perinatal outcomes, including a reduced likelihood of receiving early prenatal care and increased risk of preterm delivery, with associated adverse impacts on neonatal, developmental, and child health outcomes.

Opill's contraceptive efficacy was established with the original approval for prescription use in 1973. HRA Pharma, recently acquired by Perrigo Company plc, applied to switch norgestrel from a prescription to an over-the-counter product. The FDA requires that for approval in the nonprescription setting, the product must be shown to be used safely and effectively by consumers relying only on the nonprescription drug labeling without any assistance from a health care professional. Studies indicated that consumer understanding of information on the Opill Drug Facts label was high, suggesting their ability to properly use the drug as an over-the-counter product.

However, consumers are cautioned to take Opill at the same time every day to ensure its effectiveness. Interactions with other medications can result in decreased efficacy of Opill or the other medication, or both, potentially leading to unintended pregnancy.

Common side effects of Opill include irregular bleeding, headaches, dizziness, nausea, increased appetite, abdominal pain, cramps, or bloating. Consumers who have or have ever had breast cancer or any other form of cancer should consult a doctor before use. Opill should not be used concurrently with another hormonal birth control product.

Opill is not intended for use as emergency contraception and does not prevent pregnancy after unprotected sex. Oral contraceptives do not offer protection against transmission of HIV, AIDS, and other sexually transmitted diseases. The FDA recommends using condoms to prevent sexually transmitted diseases.

This groundbreaking approval signifies a major step forward in women's health care, providing a more accessible and convenient option for contraception.