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First OTC Birth Control Pill Approved In US Will Launch With Three-Year Market Exclusivity

by [Malcolm Spicer](#)

FDA approval of Perrigo subsidiary HRA's application comes 60 years after Rx birth control was approved in the US, one year after the application was submitted, and 13 months after the Supreme Court's Dobbs ruling. Perrigo plans to launch sales in 2024 first quarter.

[Perrigo Company PLC](#) has launched an OTC switch before, but its first with three-year market exclusivity will be Opill, approved as the first nonprescription daily oral contraceptive available in the US.

The Food and Drug Administration's approval announced on 13 July of Perrigo subsidiary HRA Pharma's supplemental new drug application, 60 years after Rx birth control's initial approval in the US and one year after the sNDA was submitted, is for a full switch of 0.075-mg norgestrel and for sales without age restrictions.

An HRA representative told HBW Insight that the Paris-based firm, which Perrigo acquired in 2022, was granted market exclusivity for Opill by the FDA.

As a first-in-class switch, and because the FDA requested a clinical trial as part of the application, Opill was eligible to receive the three-year market exclusivity highly coveted by firms proposing Rx-to-OTC switches. But eligibility does not guarantee exclusivity; the latter is granted by the FDA based on an advisory group's recommendation.

Exclusivity was introduced to the US nonprescription market in the 1984 Drug Price Competition and Patent Term Restoration Act (Public Law 98-417). Also known as the Hatch-Waxman Amendments, the law allowed marketing of generics as lower-priced equivalents of Rx drug

formulations and also granted some periods of market exclusivity for Rx innovators.

The provisions encouraged NDAs to make Rx ingredients available OTC by giving the FDA authority to grant three-year exclusivity periods for nonprescription ingredients.

Early 2024 Q1 Launch Expected

In a release, Frederique Welgryn, Perrigo's global vice president for women's health, said the progestin-only product "is now the most effective method available OTC at preventing pregnancy," and the firm is committed to making it "accessible and affordable to women and people of all ages."

Members of an FDA advisory panel unanimously voted to recommend approval of OTC Opill despite agency officials concerns about "improbable dosing" data in HRA's actual use study and about insufficient data on adolescents' comprehension of the products labeling. (Also see "[First OTC Oral Contraceptive Has Advisory Panel's Unanimous Support Despite FDA's Data Concerns](#)" - HBW Insight, 10 May, 2023.)

Dublin-based Perrigo previously said that with an FDA decision on the sNDA by a mid-August deadline set under the agency prescription drug user fee act rules, the firm expected to manufacture sufficient inventory to launch the product in early 2024.

Following the FDA announcement, it said Opill will be available in stores nationwide and online early in the first quarter.

Perrigo's first OTC switch, Nasonex 24HR (5-mg mometasone furoate) allergy nasal spray, was approved in 2022. It acquired exclusive US rights from [Merck & Co., Inc.](#) in 2018 to develop and market an OTC version of Nasonex. (Also see "[Perrigo's First National Brand, Nasonex OTC Switch, Will Have Familiar Buzz In Advertising](#)" - HBW Insight, 21 Mar, 2022.)

28-Day Blister Packs For 1, 2, 3 Or 6 Months

The FDA Center for Drug Evaluation and Research's 13 July [approval letter](#) to HRA Pharma's FDA regulatory agent in Bradenton, FL, states, "28-day blister packaging, with the required labeling on the blister packaging, is important for the safe and effective use of this product."

Packaging changes not only will require prior approval supplements, but also "may require consumer behavior testing to support the changes," the letter states.

HRA received approval for the immediate container (blister package) label and a reminder card, as well as outer carton labeling for packages with 28-count blister packs for one, two, three or six months.



THE PACKAGE FRONT, INCLUDED IN LABELING FDA APPROVED FOR OPILL, WILL BE ON STORE SHELVES AND E-COMMERCE SITES STARTING, AS PERRIGO PLANS, EARLY IN 2024. Source:

Source: FDA

Nasonex 24HR wasn't eligible for market exclusivity. While it was the first approved mometasone furoate OTC, other switches in the same class of products previously were approved.

The firm began its transition from providing generic copies to also marketing national brands in 2019 when it acquired from [GSK plc](#) US rights to an OTC proton pump inhibitors Prevacid 24HR (lansoprazole, 15 mg). (Also see "[Perrigo Prioritizes Innovating First After Following OTC Brands To Market](#)" - HBW Insight, 10 Sep, 2019.)

HRA, which collaborated with women's health and reproductive rights advocacy group Ibis Reproductive Health on OTC norgestrel studies, submitted its sNDA for the switch in July 2022. (Also see "[US FDA Has 10 Months To Provide Answer On Perrigo/HRA OTC Oral Contraceptive Application](#)" - HBW Insight, 11 Jul, 2022.)

Another application in the US for an OTC oral contraceptive is being prepared by Cadence Health Inc. The Oakland, CA-based start-up is preparing an NDA for OTC sales of a combination-ingredient formulation – levonorgestrel 0.1 mg and ethinyl estradiol 0.02mg. (Also see "[Opill AdCom Delay Not Unusual – Will Evaluation Of US OTC Switch Proposal Continue In The Norm?](#)" - HBW Insight, 2 Nov, 2022.)

HRA and UK firm Maxwellia Ltd. in 2021 received approvals in the UK for OTC switch of progestin-only daily oral contraceptives. Their identical 75-mcg desogestrel film-coated tablets are permitted for pharmacy nonprescription sales to women of childbearing age, including adolescents. (Also see "[HRA Pharma And Maxwellia To Launch The UK's First OTC Daily Contraceptives](#)" - HBW Insight, 9 Jul, 2021.)

Marketplace Test For OTC Oral Contraceptive Pricing

Senate Appropriations Committee chair Patty Murray, D-WA, is a leading advocate on Capitol Hill for making oral contraceptives available OTC as well as requiring insurers to include the products in their health plans, which is proposed in her Affordability is Access Act, [S.1698](#).

"I'm glad the FDA has followed the science to finally put over-the-counter birth control on the shelves," Murray said in a statement.

“But it’s not enough for an over-the-counter birth control pill to be available to women—it has to be affordable, too. That’s why we need to pass my legislation that would make certain insurers fully cover over-the-counter birth control without any out-of-pocket costs,” she added.

The landmark Affordable Care Act passed during former President Obama’s administration extended access to affordable contraception to millions of women by adding requirements for private health coverage and expanding Medicaid eligibility. The Affordability is Access Act would apply the requirement to OTC birth control.

Murray's S. 1698 and a matching House bill, H.R.3589, also introduced in May by Massachusetts Democrat Ayanna Pressley, have not moved out of committee.

Multiple studies have indicated women’s interest in OTC access to oral contraceptives may hinge on affordable prices or coverage by insurers. One published in 2017, based on a 2015 survey with 2,026 women and 513 teens ages 15 to 17, showed they are willing to pay out-of-pocket for the convenience of OTC access to birth control pills but not as much as they said they would in a survey four years earlier. (Also see "[OTC Oral Contraceptive Interest Could Be Price Sensitive, Study Suggests](#)" - HBW Insight, 19 Feb, 2018.)

"It's not enough for an over-the-counter birth control pill to be available to women—it has to be affordable, too." – Sen. Patty Murray

A leading US researcher in reproductive health and one of the authors of the study, Daniel Grossman of the Department of Obstetrics, Gynecology and Reproductive Sciences, University of California-San Francisco, says the Opill approval will be a marketplace test for oral contraceptive

Perrigo’s Pivot To Building Brand Market Share Boosted With Opill OTC Oral Contraceptive Approval

By [Malcolm Spicer](#)

13 Jul 2023

Year after acquiring HRA, Perrigo makes preparations to launch arguably the most anticipated OTC switch in US pharma history, Opill with 0.075-mg norgestel. Analysts estimate \$100m annual market for OTC birth control.

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pricing.

“We found that adults who were interested in using an OTC progestin-only pill were willing on average to pay a maximum of \$15 per cycle, while the maximum was \$10 for teens. Interest really fell off quickly as price increased much beyond that. I hope insurance companies, as well as Medicaid, will also cover [Opill] without requiring a prescription,” Grossman said in an email.

50 Years Since Rx Norgestrel Approval, 1 Year Since Dobbs Ruling

It has been 60 years since the FDA’s initial approval of Rx oral contraceptives, and the Opill approval comes 50 years after norgestrel was approved in the US for Rx sales. HRA discontinued sales in 2005 as combination ingredient oral contraceptives claimed dominant market share.

The approval also follows a more recent milestone in US reproductive health regulation. President Biden on 23 June issued an executive order on expanding access to birth control in the US including OTC access to oral contraceptives. (Also see "[Biden Calls For Expanding Access To Reproductive Health Care, Including OTC Oral Contraceptives](#)" - HBW Insight, 23 Jun, 2023.)

The executive order was the Biden administration’s third on reproductive health care access since the Supreme Court’s June 2022 decision in Dobbs v. Jackson (Mississippi) Women’s Health Organization, which relegated power to states to regulate access to abortion services.

Research on making oral contraceptives available OTC and drug firms’ dialogue with the FDA about submitting applications for the formulations pre-dated the Dobbs decision. In addition to galvanizing reproductive health advocates, the Supreme Court ruling heightened the drug industry and lawmakers’ attention to making a birth control pill available nonprescription. (Also see "[Allowing States To Ban Abortion Services Increases Calls For Making Birth Control Available OTC](#)" - HBW Insight, 24 Jun, 2022.)