

Overview of FDA process to switch birth control pills from prescription-only to over-the-counter status:

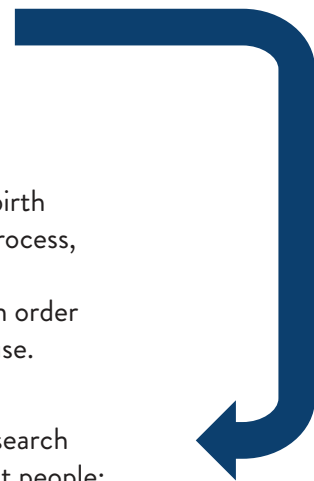
After nearly two decades of coalition-driven advocacy, research, and organizing efforts, the first-ever application for an over-the-counter (OTC) birth control pill was submitted to the US Food and Drug Administration (FDA) in 2022. Typically, the research and other activities involved in developing and submitting an Rx-to-OTC switch application, and the regulatory review can take multiple years to complete. This submission is the next step in the regulatory process and initiated the typical 10-month timeline during which the FDA reviews the data and makes a decision on whether to approve the product for OTC use.



For a prescription-only product, like birth control pills, to be made available OTC, a pharmaceutical company must submit an Rx-to-OTC switch application to the FDA.



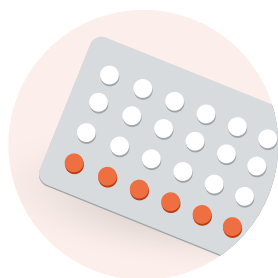
There are many formulations of birth control pills. Through the FDA process, an application would need to be submitted for each formulation in order for it to be considered for OTC use.



As part of the Rx-to-OTC switch application, the FDA requires research demonstrating that the product meets criteria for OTC use and that people:



- Can understand how to use the product by reading the Drug Facts Label on the back of the pack
- Are independently able to determine, without oversight from a health care provider, if the pill is appropriate for them to use by reading the label
- Can take the product as indicated on the label



Once this important research is completed, it is submitted in an application to the FDA and the agency has 10 months to make a decision on whether to approve the product for OTC use. During the review process, the FDA may organize an advisory committee meeting to hear expert advice and public testimony.



Based on the internal review and input from the advisory committee, the FDA will determine whether to approve the application. If approved, the product can be made available on the shelf without a prescription.