

Supplement to the Petition to the FDA to Ban Third Generation Oral
Contraceptives Containing Desogestrel due to Increased Risk of Venous
Thrombosis (Petition # 2007P-0044)

February 9, 2007

Andrew Von Eschenbach, M.D., Commissioner
U.S. Food and Drug Administration
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Von Eschenbach:

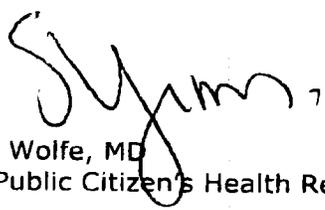
I am writing to clarify/modify one sentence in our petition filed earlier this week concerning Third Generation Oral Contraceptives. The sentence is: "Third generation OCs contain desogestrel (available in the US), norgestimate or gestodene (neither are available in the US), while second generation OCs contain norgestrel, levonorgestrel, or norethindrone."

Although norgestimate was developed after the second generation oral contraceptives and is therefore sometimes referred to as a third generation progestagen, because it is partially metabolized to a second generation progestagen and because the studies showing increased risk of third generation pills are almost exclusively limited to desogestrel or gestodene, many researchers consider it more like a second generation progestagen. In addition, products containing norgestimate are available in the U.S.

We therefore want to modify our petition (this sentence) to state:

Third generation OCs contain desogestrel (available in the US), or gestodene (not available in the US), while second generation OCs contain norgestrel, levonorgestrel, norgestimate or norethindrone.

Sincerely,


Sidney M. Wolfe, MD
Director, Public Citizen's Health Research Group

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