

## **FDA Approves New Combination Product Oral Contraceptive**

The U.S. Food and Drug Administration today approved Natazia, a combination hormonal tablet for use as an oral contraceptive.

Natazia contains two female hormones, an estrogen (estradiol valerate) and a progestin (dienogest), and is the first four-phasic oral contraceptive marketed in the United States. Four-phasic refers to the doses of progestin and estrogen varying at four times throughout each 28-day treatment cycle.

"Nearly 12 million women in the United States and more than 100 million women worldwide currently use oral contraceptives," said Scott Monroe, M.D., director of FDA's Division of Reproductive and Urologic Products. "The approval of Natazia provides another option for women who choose to use an oral contraceptive as their method of contraception."

The safety and efficacy of Natazia as an oral contraceptive was evaluated in two multicenter phase 3 clinical trials in North America and Europe. The trials involved 1,867 women and nearly 30,000 28-day treatment cycles. Natazia was found to be effective as a hormonal contraceptive in both studies.

The most common side effects observed with Natazia include irregular bleeding, breast tenderness, headaches, nausea and vomiting, increased weight, and acne. Women older than 35 who smoke should not use this product. Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive use.

Natazia is manufactured by Bayer HealthCare Pharmaceuticals of Wayne, N.J.