



## Yaz

Treatment for [Acne](#), [Contraception](#), [Premenstrual Dysphoric Disorder](#)

### Berlex Receives Approvable Letter From FDA on the Company's Second Oral Contraceptive Containing Drospirenone

0 tweets Approval is Pending Submission of Additional Data Regarding Unique Yaz Dosing Regimen

tweet MONTVILLE, N.J., November 18, 2004 -- The US Food and Drug Administration (FDA) has issued an approvable letter to Berlex, Inc., a U.S. affiliate of Schering AG, Germany (NYSE: SHR; FSE: SCH), for its new oral contraceptive containing 20 mcg ethinyl estradiol and 3 mg drospirenone (drsp), called Yaz. The FDA has requested additional data to support this pill's unique dosing regimen-24 days of active pills followed by 4 days of placebo (inactive) pills. Oral contraceptives typically have a regimen of 21 days of active pills and 7 days of placebo.

In response to this letter, Berlex will submit data to support the clinical benefits of the additional three days of active pills in each cycle. The submission will include data from two recently completed, placebo-controlled studies among patients with symptoms of premenstrual dysphoric disorder (PMDD), a more severe form of PMS. In addition to seeking an indication as an oral contraceptive with this submission, Berlex will also seek approval for Yaz as a treatment option for women with symptoms of PMDD who desire pregnancy prevention.

"Upon approval, Yaz will add to our rich product portfolio that has helped us become the global leader in contraception, and will build upon the success of Yasmin, currently the number one branded oral contraceptive in the U.S.," says Reinhard Franzen, President and CEO of Berlex.

"Our studies showed that treatment with Yaz results in a highly statistically significant reduction of the symptoms of PMDD as compared to placebo," says Marie Foegh, MD, DSc, Vice President, Medical Affairs at Berlex. "We believe this effect is due to the shortened pill-free interval of its dosing regimen, combined with drospirenone, which, unlike other progestins, exhibits anti-mineralocorticoid and anti-androgenic activity." Berlex plans to submit the additional data by the end of 2004, with a final approval in 2005.

#### Important information about oral contraceptives and Yasmin

Yasmin contains 3 mg of the progestin drospirenone that has anti-mineralocorticoid activity, including the potential for hyperkalemia in high-risk patients, comparable to a 25-mg dose of spironolactone. Yasmin should not be used by patients with conditions that predispose to hyperkalemia (ie, renal insufficiency, hepatic dysfunction, or adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium levels checked during the first treatment cycle.

Oral contraceptives (OCs) do not protect against HIV infection and other sexually transmitted diseases. The use of OCs is associated with increased risks of several serious side effects. Cigarette smoking increases the risk of serious cardiovascular side effects; women who take OCs are strongly advised not to smoke.

#### About Berlex

Committed to addressing unmet medical needs, Berlex, a U.S. affiliate of Schering AG, Germany (NYSE: SHR; FSE: SCH), develops and markets diagnostic imaging agents, treatments in the areas of female health care and dermatology, as well as specialized therapeutics for life-threatening and disabling diseases in the fields of the central nervous

and cardiovascular systems, oncology, and gastroenterology. Berlex has business operations in New Jersey, California and Washington.

For more information, please visit [www.berlex.com](http://www.berlex.com).

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