

Press Release

For Immediate Release

## **Glenmark Generics received Two Oral Contraceptives product approval from the USFDA**

- **With these approvals, Glenmark is now authorized to distribute seven hormones/OCs in the US**
- **The two products approved are Norethindrone and Ethinyl Estradiol (Alyacen™1/35) Tablets USP & Norethindrone and Ethinyl Estradiol (Alyacen™ 7/7/7) Tablets USP**

**January 20, 2012:** Glenmark Generics Inc., USA, a subsidiary of Glenmark Generics Ltd, today announced they have been granted final approval for two abbreviated new drug applications (ANDA) by the United States Food and Drug Administration (U.S. FDA).

Today's approvals are for the oral contraceptive products Norethindrone and Ethinyl Estradiol (Alyacen™1/35) Tablets USP, 1 mg/0.035 mg and Norethindrone and Ethinyl Estradiol (Alyacen™ 7/7/7) Tablets USP, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg and 1 mg/0.035 mg, the generic equivalents of Ortho-McNeil Janssen's Ortho-Novum® 1/35-28 Tablets and Ortho-Novum® 7/7/7-28 Tablets, respectively.

Alyacen™1/35 and Alyacen™ 7/7/7 Tablets are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. According to IMS Health for the 12 month period ending September 2011, these products achieved total market sales of approximately USD 96 million.

The Company's current portfolio consists of 75 generic products authorized for distribution in the U.S. market and 41 ANDA's filed with the U.S. FDA pending approval. In addition to these internal filings, GGI continues to identify and explore external development partnerships to supplement and accelerate the growth of the existing pipeline and portfolio.

### **About Glenmark Generics Limited.**

Glenmark Generics Limited (GGL) is a subsidiary of Glenmark Pharmaceuticals Limited (Glenmark) and aims to be a global integrated Generic and API leader. GGL has an established presence in North America, a developing EU presence and Argentina and maintains marketing front-ends in these countries. It primarily sells its FDF products in the United States ("US") and the European Union ("EU"), as well as its oncology FDF products in South America. The Company supplies APIs to customers in approximately 63 countries, including the US, various countries in the EU, South America and India.

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