Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: February 27, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Glenmark Generics Inc. Nationwide Recall of Seven (7) Lots of Norgestimate and Ethinyl Estradiol Tablets Due to Possibility of Out of Sequence Tablets

SUGGESTED ACTION: **Unclassified Recall: Glenmark Generics Inc. USA today issued a voluntary, nationwide, consumer-level recall of seven (7) lots of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg. The recall is being implemented because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch. Patients who have the affected product (lot numbers are provided below) should notify their physician and return the product to the pharmacy. If any recalled products are found, please notify this office at 317-233-7360.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Glenmark Generics Inc. Announces a Nationwide Recall of Seven (7) Lots of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (Generic) Due to Possibility of Out of Sequence Tablets

Contact:
Consumer:
1-(888)721-7115

FOR IMMEDIATE RELEASE - February 24, 2012 - Glenmark Generics Inc. USA today issued a voluntary, nationwide, consumer-level recall of seven (7) lots of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg. The recall is

being implemented because of a packaging error, where select blisters were rotated 180 degrees within the card, reversing the weekly tablet orientation and making the lot number and expiry date visible only on the outer pouch. Any blister for which the lot number and expiry date is not visible is subject to recall. This packaging error is limited to the seven (7) lots listed in the table below of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg. This product is used as an oral contraceptive indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. These packaging defects do not pose any immediate health risks. However, consumers exposed to affected packaging should begin using a non-hormonal form of contraception immediately. Patients who have the affected product (lot numbers are provided below) should notify their physician and return the product to the pharmacy.

These tablets were manufactured and packaged by Glenmark Generics Ltd. India. and are distributed by Glenmark Generics Inc. USA. This product is distributed to wholesalers and retail pharmacies nationwide between September 21, 2011 and December 30, 2011. This product is distributed by Glenmark Generics Inc. only in the USA.

Lot numbers of affected packs of Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (Generic), are as follows:

NDC	Lot Nos	Expiration
68462-565-29	04110101	07/31/2013
	04110106	07/31/2013
	04110107	07/31/2013
	04110114	08/31/2013
	04110124	08/31/2013
	04110129	08/31/2013
	04110134	09/30/2013

This packaging related issue was discovered when Glenmark received a complaint from a consumer stating that she received one blister pack in which the tablets were packaged in reverse order. The correct packaging configuration of this product has 3 pouch packs packaged in a carton and each pouch pack has one blister which contains 28 tablets (seven tablets each of a different strength and inactive tablets) in which the sequence is white to off-white tablets on top row and inactive light green tablets in bottom row (correctly packaged blister packs are pictured here):

1. Each white to off white tablet contains 0.18 mg of the progestational compound, norgestimate USP, together with 0.035 mg of the estrogenic compound, ethinyl estradiol USP.
2. Each light blue tablet contains 0.215 mg of the progestational compound, norgestimate USP, together with 0.035 mg of the estrogenic compound, ethinyl estradiol USP.
3. Each blue tablet contains 0.25 mg of the progestational compound, norgestimate USP, together with 0.035 mg of the estrogenic compound, ethinyl estradiol USP.
4. Each light green tablet contains inert ingredients only.

Any adverse events that may be related to the use of these products should be reported to Glenmark Generics Inc., USA at 1-(888)721-7115 (8 AM to 5 PM Mon-Fri EST) or to FDA's MedWatch Program either online, by regular mail or by fax.

Online:	www.fda.gov/medwatch/report.htm
Regular Mail:	Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to the address on the pre-addressed form.
Fax:	1-800-FDA-0178

Glenmark has responded rapidly to ensure that its products continue to meet the company's high quality standards. The safety of patients who take our medicines is our first priority. The cause was identified and corrected immediately. At this time, there remains sufficient supply of unaffected lots of material in the marketplace to support demand.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Glenmark Generics Inc.

Glenmark Generics Inc. (GGI), USA is the North American division of Glenmark Generics Ltd. dedicated to the manufacture, marketing and distribution of generic pharmaceutical products. GGI (formerly Glenmark Pharmaceuticals Inc., USA) established operations in 2003 and was a subsidiary of Glenmark Pharmaceuticals Limited. In a short span of five years, the Company saw exponential growth in all areas and gained an impressive reputation in the industry as a driving force among its competition. Today, GGI is authorized to distribute around 55 products which generates a finished dosage marketing portfolio yielding over 175 sku's (a mix of solid oral dosage and semi-solid preparations). GGI's products have high market penetration rates and double digit share almost across the board. Outstanding service levels can be attributed to the dedicated customer service teams put in place to ensure the smooth transition of products from the warehouse to customers.

Glenmark Generics Inc. Norgestimate and Ethinyl Estradiol Tablets USP, 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg (Generic) Photo: