

US recalls India-made birth control pills

February 27 2012

A batch of birth control pills manufactured in India for US distribution has been recalled due to a packaging error that could make the pills ineffective, US health authorities said on Monday.

Seven lots of generic norgestimate and ethinyl estradiol tablets were recalled by Glenmark Generics Inc. USA, the US [Food and Drug Administration](#) said.

The company said the tablets were manufactured and packaged by Glenmark Generics Ltd. India. and distributed to wholesalers and [retail pharmacies](#) across the United States between September 21, 2011 and December 30, 2011.

"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](#)," Glenmark said in a statement.

It was not immediately clear how many packets were affected by the error, which rotated some of the pills by 180 degrees out of the usual sequential order and left 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," Glenmark added in a statement.

Doctors urged women who may have been taking the pills to

immediately begin using a non-hormonal form of contraception, inform their [health care provider](#) immediately and take a [pregnancy test](#) if they have any symptoms of pregnancy.

"This is extremely disturbing," said Steven Goldstein, an obstetrician-gynecologist at New York University Langone Medical Center and Professor at the NYU School of Medicine, adding the recall raised new concerns about the safety of foreign-made generics.

"This problem with generics manufactured outside of the USA is of great concern to me as a clinician. I often allow and encourage patients to try generics as long as they do not have nuisance side effects however I have always assumed them of equal quality control to the branded products."

Glenmark Generics has operated its manufacturing plant in India since 2003.

The recall is the third to affect US consumers in the past six months involving contraceptives.

On February 1, US pharmaceutical giant Pfizer recalled one million packets of [birth control pills](#) over a similar packaging error, though those pills were manufactured in the United States.

A separate recall was issued in September 2011 by the pharmaceutical company Qualitest in Alabama, due to packaging errors that affected 1.4 million packets of birth control pills distributed in 2011.

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