Lo/Ovral-28 (Norgestrel/EthinylEstradiol) Tablets: Recall - Possibility of Inexact Tablet Counts or Out of Sequence Tablets

ISSUE: Pfizer Inc. notified healthcare professionals and consumers that it recalled 14 lots of Lo/Ovral-28 (norgestrel and ethinyl estradiol) Tablets and 14 lots of Norgestrel and Ethinyl Estradiol Tablets (generic) for customers in the U.S. market. An investigation by Pfizer found that some blister packs may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. 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.

BACKGROUND: These products are oral contraceptives indicated for the prevention of pregnancy. These products are packaged in blister packs containing 21 tablets of active ingredients and seven tablets of inert ingredients. Correct dosing of this product is important in avoiding the associated risks of an unplanned pregnancy.

RECOMMENDATION: Patients who have the affected product should notify their physician and return the product to the pharmacy. See the Press Release for a list of affected lot numbers.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[1]
- Download form[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178