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 1, 2012

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

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

SUBJECT: Pfizer Inc. Recall

SUGGESTED

ACTION: **Unclassified Recall; 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; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. These products are oral contraceptives indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. These tablets were manufactured and packaged by Pfizer Inc., commercialized by Akrimax Rx Products and labeled under the Akrimax Pharmaceuticals brand. This product is distributed to warehouses, clinics and retail pharmacies nationwide. Detail information is not available at this time. In addition, 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.

Pfizer Announces Voluntary Nationwide Recall of Lo/Ovral®-28 and Norgestrel/Ethinyl Estradiol Tablets Due to Possibility of Inexact Tablet Counts or Out of Sequence Tablets

Contact:
Consumer:
1-877-509-3935

Media:
Grace Ann Arnold – Media
(845) 602-4768
Graceann.Arnold@Pfizer.com

FOR IMMEDIATE RELEASE - January 31, 2012 - NEW YORK, N.Y. – Pfizer Inc. announced today that it has voluntarily 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. The cause was identified and corrected immediately.

These products are oral contraceptives indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. These tablets were manufactured and packaged by Pfizer Inc., commercialized by Akrimax Rx Products and labeled under the Akrimax Pharmaceuticals brand. This product is distributed to warehouses, clinics and retail pharmacies nationwide.

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 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. Correctly packaged blister packs are pictured here.

Any adverse events that may be related to the use of these products should be reported to Akrimax Medical Information at 1-877-509-3935 (8 AM to 7 PM Mon-Fri CST) or to FDA's Med Watch Program either online, by regular mail or by fax.

Online:	www.fda.gov/medwatch/report.htm[1]
Regular Mail:	Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to the address on the pre-addressed form.
Fax:	1-800-FDA-0178

Pfizer 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.

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

Lot numbers of affected packs of Lo/Ovral®-28 (norgestrel and ethinyl estradiol)Tablets and Norgestrel and Ethinyl Estradiol Tablets (generic) follow on the table below:

NDC	Product	Lot	Expiration	Configuration/Count
24090-801-84	LO/OVRAL® 28	E15678	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15679	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15686	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15687	01/31/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15690	01/31/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15698	01/31/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E15700	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E80434	07/31/2013	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	E80438	08/31/2013	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	F36908	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	F36909	02/28/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	F43915	03/31/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	F43926	03/31/2014	6 Pilpacks® of 28 tablets each
24090-801-84	LO/OVRAL® 28	F43927	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	E15677	08/31/2013	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	E15704	01/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	E15706	01/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	E80440	08/31/2013	6 Pilpacks® of 28 tablets each
24090-	Norgestrel 0.3 mg/Ethinyl	F16388	01/31/2014	6 Pilpacks® of 28 tablets

961-84	Estradiol 0.03 mg			each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F16390	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F22132	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F31330	02/28/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F36911	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F36913	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F43924	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F43925	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F43934	03/31/2014	6 Pilpacks® of 28 tablets each
24090-961-84	Norgestrel 0.3 mg/Ethinyl Estradiol 0.03 mg	F53238	03/31/2014	6 Pilpacks® of 28 tablets each

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Photo: Product Labels[5]