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: June 7, 2012

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

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

SUBJECT: Sandoz Recall

SUGGESTED ACTION: **Unclassified Recall; 10 lots of its generic oral contraceptive Introvale® in the US, following a recent report of a packaging flaw; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recalled products were distributed only in the US between January 2011 and May 2012. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Sandoz US Announces Precautionary Recall Of Oral Contraceptive Introvale®, Following Report Of Packaging Flaw

Contact
Consumer:
800-525-2492, or
609-627-5287
qa.druginfo@sandoz.com

Media:
609-827-8500

FOR IMMEDIATE RELEASE - June 5, 2012 - Sandoz is conducting a voluntary recall of 10 lots of its generic oral contraceptive Introvale® in the US, following a recent report of a packaging flaw. The probability of this packaging flaw causing serious adverse health consequences is remote and Sandoz is not aware of any reports of related adverse events. This recall is being undertaken as a precautionary measure to minimize any potential of patients being impacted. The recall is being conducted with the knowledge of the Food and Drug Administration.

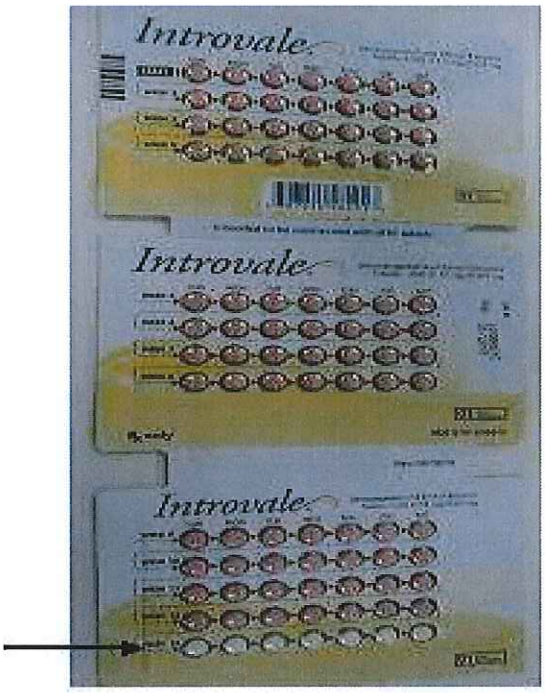
The lot numbers involved in the recall are as follows: LF00478C, LF00479C, LF00551C, LF00552C, LF00687C, LF00688C, LF00763C, LF00764C, LF00765C and LF01261C. These lots were distributed only in the US between January 2011 and May 2012.

The recall was decided after a consumer reported that the white placebo tablets were mistakenly in the ninth row (labeled "Week 9") of the 13-row blister card, rather than in the correct position in the 13th and final row (labeled "Week 13"). Each three-month blister card contains 84 peach-colored active tablets and seven white placebo tablets in 13 rows, each representing one week (see figure below). While the white placebo tablets can be clearly distinguished from the peach-colored active tablets, the risk of an unintended pregnancy for a patient taking the wrong tablet over several days cannot be excluded.

In the unlikely event that a patient finds a white placebo tablet in any position other than the 13th and final row (Week 13), they should immediately begin using a non-hormonal form of contraception. They should also immediately contact their healthcare professional as well as Sandoz to report the finding via the Sandoz Drug Information Direct Line at 800-525-2492, 24 hours/day, seven days a week, or via email at qa.druginfo@sandoz.com.

Patients or their healthcare provider may also report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax as indicated below:

- Online: http://www.fda.gov/medwatch/report.htm[1]
- Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2]. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178



Sandoz Oral Contraceptive Introvale®, representative three-month blister card. As shown above, the white placebo tablets should be in Row 13, which represents Week 13.

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