Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 8, 2013

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

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

SUBJECT: Sandoz USA Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; One lot of its Estarylla® (norgestimate and ethinyl estradiol) tablets in the US, following a customer report of a placebo tablet present in a row of active tablets on one pack; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The lot number, expiration date, and NDC code of the recalled lot is: LF01213A, expiration date 02/2014, NDC 00781-4058-15. It is supplied in cartons containing 3 blister cards of 28 tablets each. This lot was distributed to the US market only. Estarylla is manufactured for Sandoz by a third party manufacturer. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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 Voluntary Nationwide Recall of One Lot of Estarylla®

Contact
Consumer:
800-525-2492
qa.druginfo@sandoz.com

Media:
Chris Lewis
609-627-5287

FOR IMMEDIATE RELEASE - July 03, 2013 - Princeton, New Jersey, – Sandoz is conducting a voluntary nationwide recall to the retailer level of one lot of its Estarylla® (norgestimate and ethinyl estradiol) tablets in the US, following a customer report of a placebo tablet present in a row of active tablets on one pack.

Estarylla is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception. [1]

Sandoz is not aware of any reports to date of related adverse events. An internal medical assessment concludes that the probability of adverse health events is minimal, as the packaging flaw is easily visible and the risk of pregnancy occurring after non-administration of one blue tablet is low. The recall is in line with Sandoz' commitment to patient safety, and is being conducted with the knowledge of the US Food and Drug Administration (FDA).

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In the event that a patient experiences an adverse reaction or quality problem involving this product, they should immediately contact their healthcare professional as well as Sandoz to report the finding. The Sandoz Drug Information Direct Line is open at 800-525-2492, 24 hours/day, seven days a week, or reports can be made via email at qa.druginfo@sandoz.com.

Any adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA MedWatch Adverse Events Program either online, by regular mail, or by fax.

- **Online**: http://www.fda.gov/MedWatch/report.htm[1]
- **Regular mail**: use postage-paid, pre-addressed Form FDA3500 available at http://www.fda.gov/MedWatch/getforms.htm[2]
- **Fax**: 1-800-FDA-0178

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "being investigated," "probability," or similar expressions, or by express or implied discussions regarding the recall of Estarylla®, or regarding potential future revenues from Estarylla®. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known

and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; uncertainties regarding actual or potential legal proceedings, including, among others, product liability litigation and government investigations; competition in general; government, industry and general public pricing pressures; unexpected issues in remedying the Estarylla® manufacturing process; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Division of the Novartis group, is the second-largest generic pharmaceuticals company globally, offering a broad range of about 1,000 high-quality, affordable products that are no longer protected by patents. With approximately 25,000 employees in 140 countries, Sandoz holds the #1 position globally in biosimilars as well as generic injectables, ophthalmics, dermatology, and antibiotics. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments, and hormone therapies. Sandoz develops, produces, and markets these medicines along with pharmaceutical and biotechnological active substances and anti -infectives. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), Oriel Therapeutics (US), and Fougera Pharmaceuticals (US). In 2012, Sandoz posted sales of USD 8.7 billion.

[1] For full safety information, please see the Estarylla® prescribing information, available in the Product Catalog at www.us.sandoz.com[3].