Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 21, 2013

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; Sandoz is conducting a voluntary nationwide recall to the hospital/user level of two lots of its Methotrexate Sodium, USP, 25 mg/mL, 40 mL vial injectable product in the US, due to the discovery of particulate matter in vials during routine quality examination of retention samples at the manufacturer. The lot numbers and expiration dates of the two recalled lots are: CL0996 (expiration date 12/2013) and CJ4948 (expiration date 05/2013).; Information provided in case of consumer inquiry.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The recalled products were distributed nationally across the US and to a single foreign country (Poland). Detail 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 two lots of Methotrexate Sodium, USP, Injectable Vials, 25mg/mL, 40mL vials

Contact:
Consumer:
800-525-2492

Media:
Chris Lewis
1 609 627 5287

Neil Moorhouse
49 8024 476 2597

FOR IMMEDIATE RELEASE - May 20, 2013 - Sandoz is conducting a voluntary nationwide recall to the hospital/user level of two lots of its Methotrexate Sodium, USP, 25 mg/mL, 40 mL vial injectable product in the US, due to the discovery of particulate matter in vials during routine quality examination of retention samples at the manufacturer. The product is preservative free. The particulates are not associated with microbial contamination. Administration is by physicians/health care professionals.

Methotrexate is an antimetabolite used in the treatment of neoplastic diseases, severe psoriasis, and rheumatoid arthritis, including polyarticular juvenile rheumatoid arthritis. [1]

Particulate matter in parenteral drugs has been recognized as a potential health hazard. Parenteral injection of drug from the affected lots can lead to microembolisation in areas where the particles lodge. Following intravenous (i.v.) injections, this is in all likelihood the lung. Intrathecal injections are very unlikely with the affected product. In the event of intrathecal administration areas of particle lodging are most likely the areas of spinal fluid resorption. Clinical symptoms are not to be expected from these microemboli. Sandoz is not aware of any reports of related adverse events. Patient safety is our number one priority.

The lot numbers and expiration dates of the two recalled lots are: CL0996 (expiration date 12/2013) and CJ4948 (expiration date 05/2013). These lots were distributed nationally across the US and to a single foreign country (Poland).

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 be reported to the US Food and Drug Administration's (FDA) MedWatch Adverse Events 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 FDA3500 available at www.fda.gov/MedWatch/getforms.htm[2]
- Fax: 1-800-FDA-0178

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

This recall is being conducted with the knowledge of the US FDA.

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 methotrexate injection, or regarding potential future revenues from methotrexate injection. 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 methotrexate injection 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.

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RSS Feed for FDA Recalls Information[4] [what's this?[5]]

Photo: Product Labels[6]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[7]

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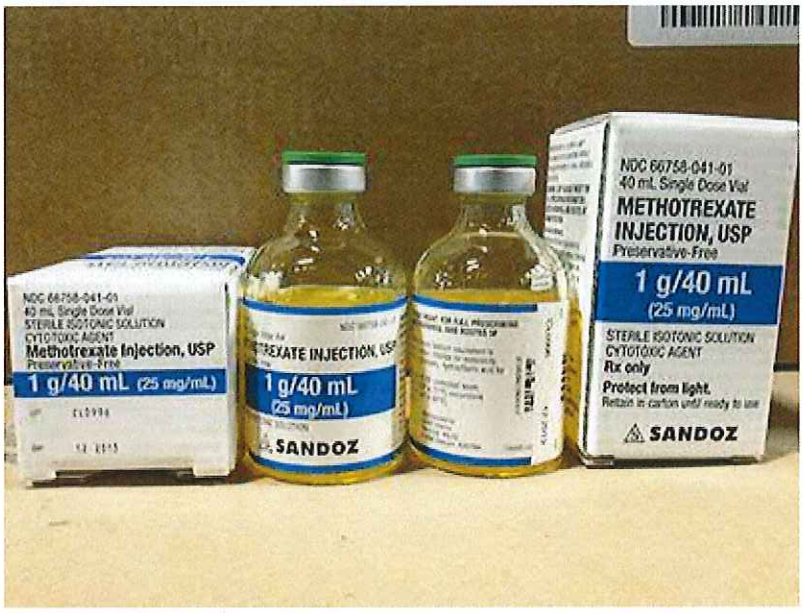
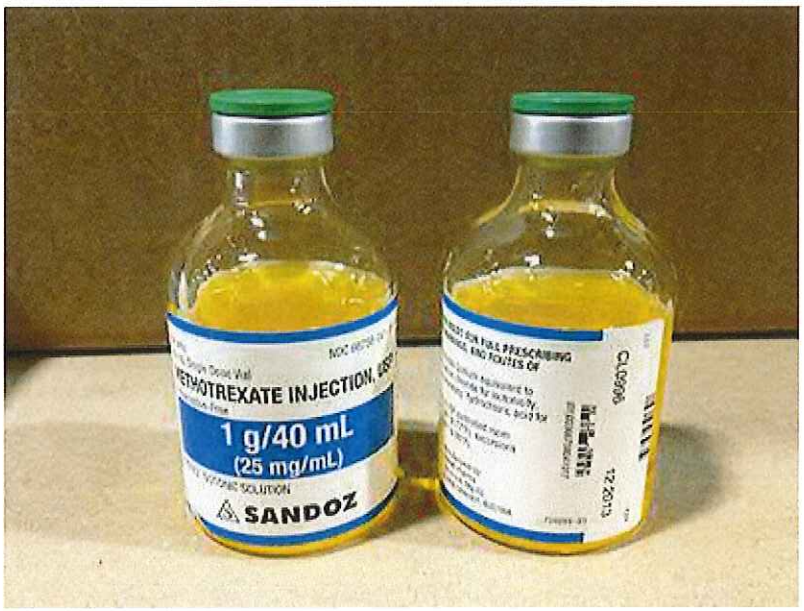
Photos




METHOTREXATE INJECTION,
1 g/40 mL
(25 mg/mL)
SANDOZ