



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

**DATE:** March 20, 2014

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

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

**SUBJECT:** Terra-Medica, Inc. - RECALL [Drug]

**AFFECTED PRODUCT:** Pleo-FORT, Pleo-QUENT, Pleo-NOT, Pleo-STOLO, Pleo-NOTA-QUENT, and Pleo-EX homeopathic drug products in liquid, tablet, capsule, ointment, and suppository forms.

**SUMMARY:** Unclassified Recall; These products have the potential to contain penicillin or derivatives of penicillin, which may be produced during the fermentation process.

The products are used as homeopathic drugs and have a label stating "Distributed by SANUM USA Corp." The affected products are identified by package size, batch (lot) number and expiry date (ranging from March 2014 – May 2018) and can be found in the table attached to this recall. The batch number can be located at the side panel on the label.

The affected products were distributed nationwide through health care practitioners, who may have sold the products through websites.

**SUGGESTED ACTION:** For consumer inquiry only. Consumers with questions regarding this recall can contact Terra-Medica's Customer Service Department at (888) 415-0535, ext. 1, Monday through Friday between 8-5pm, Pacific Time Zone, or their health care practitioner that distributed the product.

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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.



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essential public health services.

## **Terra-Medica Issues Voluntary Nationwide Recall of Specified Lots of Pleo Homeopathic Drug Products Due to the Potential for Undeclared Penicillin**

**Contact:**

Consumer:

1-888-415-0535

[terry@biomedicine.com](mailto:terry@biomedicine.com)

**FOR IMMEDIATE RELEASE** - March 18, 2014 - Terra-Medica, Inc. is voluntarily recalling 56 lots of Pleo-FORT, Pleo-QUENT, Pleo-NOT, Pleo-STOLO, Pleo-NOTA-QUENT, and Pleo-EX homeopathic drug products in liquid, tablet, capsule, ointment, and suppository forms to the consumer level. FDA has determined that these products have the potential to contain penicillin or derivatives of penicillin, which may be produced during the fermentation process.

In patients who are allergic to beta-lactam antibiotics, even at low levels, exposure to penicillin can result in a range of allergic reactions from mild rashes to severe and life-threatening anaphylactic reactions. To date, Terra-Medica has not received any reports of adverse events related to this recall, nor any reports of product tests indicating penicillin content in the products.

The products are used as homeopathic drugs and have a label stating "Distributed by SANUM USA Corp." The affected products are identified by package size, batch (lot) number and expiry date (ranging from March 2014 – May 2018) in the table accompanying this release. The batch number can be located at the side panel on the label. The affected products were distributed nationwide through health care practitioners, who may have sold the products through websites.

Terra-Medica is notifying its customers by letter and email and is arranging for return of all recalled products. Consumers and distributors that have product which is subject to the recall should stop using the products and return them to the point of purchase.

Consumers with questions regarding this recall can contact Terra-Medica's Customer Service Department at (888) 415-0535, ext. 1, Monday through Friday between 8-5pm, Pacific Time Zone, or their health care practitioner that distributed the product. Consumers should contact their physician or healthcare provider if they have experienced reactions while taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to Terra Medica or the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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

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

| Product Name        | Potency | Pharmaceutical Form | Package Size | Batch # | Expiry Date |
|---------------------|---------|---------------------|--------------|---------|-------------|
| PLEO-NOT            | 5X      | Portable sips       | 10 x 1ml     | 07099   | 08/2014     |
| PLEO-NOT            | 5X      | Portable sips       | 10 x 1ml     | 15090   | 08/2015     |
| PLEO-NOT            | 5X      | Portable sips       | 10 x 1ml     | 06120   | 11/2015     |
| PLEO-NOT            | 5X      | Portable sips       | 10 x 1ml     | 19023   | 01/2018     |
| PLEO-NOT            | 5X      | Portable sips       | 50 x 1ml     | 07099   | 08/2014     |
| PLEO-NOT            | 5X      | Portable sips       | 50 x 1ml     | 15090   | 08/2014     |
| PLEO-NOT            | 5X      | Portable sips       | 50 x 1ml     | 01110   | 10/2015     |
| PLEO-NOT            | 5X      | Portable sips       | 50 x 1ml     | 06120   | 11/2015     |
| PLEO-NOT            | 5X      | Portable sips       | 50 x 1ml     | 19023   | 01/2018     |
| PLEO-NOT            | 6X      | Portable sips       | 10 x 1ml     | 25050   | 04/2015     |
| PLEO-NOT            | 6X      | Portable sips       | 50 x 1ml     | 25050   | 04/2015     |
| PLEO-NOT            | 7X      | Portable sips       | 10 x 1ml     | 20010   | 12/2014     |
| PLEO-NOT            | 7X      | Portable sips       | 50 x 1ml     | 20010   | 12/2014     |
| PLEO-NOT            | 5X      | Drops               | 10ml         | 21049   | 03/2014     |
| PLEO-NOT            | 5X      | Drops               | 10ml         | 13059   | 04/2014     |
| PLEO-NOT            | 5X      | Drops               | 10ml         | 09080   | 07/2015     |
| PLEO-NOT            | 5X      | Drops               | 10ml         | 15100   | 09/2015     |
| PLEO-NOT            | 5X      | Drops               | 10ml         | 24092   | 08/2017     |
| PLEO-NOT            | 5X      | Tablets             | 20pcs        | 15070   | 06/2015     |
| PLEO-NOT            | 5X      | Tablets             | 20pcs        | 24072   | 06/2017     |
| PLEO-NOT            | 3X      | Ointment            | 30g          | 03051   | 04/2014     |
| PLEO-NOT            | 3X      | Ointment            | 30g          | 13072   | 06/2015     |
| PLEO-NOT            | 3X      | Ointment            | 30g          | 21033   | 04/2016     |
| PLEO-NOT            | 3X      | Suppositories       | 10pcs        | 1080    | 07/2015     |
| PLEO-NOT            | 3X      | Suppositories       | 10pcs        | 1102    | 09/2017     |
| PLEO-NOT            | 4X      | Capsules            | 20pcs        | 14010   | 12/2014     |
| PLEO-NOT            | 4X      | Capsules            | 20pcs        | 11080   | 08/2015     |
| PLEO-NOT            | 4X      | Capsules            | 20pcs        | 12092   | 07/2017     |
| PLEO-NOTA-<br>QUENT | 5X      | Drops               | 10ml         | 04062   | 05/2017     |
| PLEO-NOTA-<br>QUENT | 5X      | Drops               | 10ml         | 06062   | 05/2017     |
| PLEO-QUENT          | 5X      | Portable sips       | 10 x 1ml     | 13090   | 08/2015     |
| PLEO-QUENT          | 5X      | Portable sips       | 50 x 1ml     | 13090   | 08/2015     |
| PLEO-QUENT          | 5X      | Drops               | 10ml         | 15129   | 11/2014     |
| PLEO-QUENT          | 5X      | Drops               | 10ml         | 12040   | 03/2015     |
| PLEO-QUENT          | 5X      | Drops               | 10ml         | 01081   | 08/2016     |
| PLEO-QUENT          | 4X      | Capsules            | 20pcs        | 25030   | 04/2015     |
| PLEO-QUENT          | 4X      | Capsules            | 20pcs        | 27101   | 09/2016     |
| PLEO-QUENT          | 3X      | Suppositories       | 10pcs        | 2089    | 06/2014     |
| PLEO-QUENT          | 3X      | Suppositories       | 10pcs        | 3031    | 03/2016     |
| PLEO-FORT           | 5X      | Portable sips       | 10 x 1ml     | 15030   | 02/2015     |
| PLEO-FORT           | 5X      | Portable sips       | 10 x 1ml     | 12122   | 11/2017     |
| PLEO-FORT           | 5X      | Portable sips       | 50 x 1ml     | 15030   | 02/2015     |
| PLEO-FORT           | 5X      | Portable sips       | 50 x 1ml     | 12122   | 11/2017     |
| PLEO-FORT           | 5X      | Drops               | 10ml         | 23109   | 09/2014     |
| PLEO-FORT           | 5X      | Drops               | 10ml         | 08030   | 02/2015     |



|            |    |               |          |       |         |
|------------|----|---------------|----------|-------|---------|
| PLEO-FORT  | 5X | Drops         | 10ml     | 12032 | 02/2017 |
| PLEO-FORT  | 5X | Drops         | 10ml     | 26043 | 03/2018 |
| PLEO-FORT  | 5X | Tablets       | 20 pcs   | 27100 | 09/2015 |
| PLEO-FORT  | 5X | Tablets       | 20 pcs   | 29100 | 10/2015 |
| PLEO-FORT  | 5X | Tablets       | 20 pcs   | 25013 | 01/2018 |
| PLEO-FORT  | 3X | Suppositories | 10pcs    | 3110  | 10/2015 |
| PLEO-FORT  | 3X | Suppositories | 10pcs    | 1112  | 10/2017 |
| PLEO-FORT  | 4X | Capsules      | 20pcs    | 24030 | 02/2015 |
| PLEO-FORT  | 4X | Capsules      | 20pcs    | 14062 | 05/2017 |
| PLEO-EX    | 5X | Portable sips | 10 x 1ml | 09020 | 01/2015 |
| PLEO-EX    | 5X | Portable sips | 10 x 1ml | 03052 | 04/2017 |
| PLEO-EX    | 5X | Portable sips | 50 x 1ml | 09020 | 01/2015 |
| PLEO-EX    | 5X | Portable sips | 50 x 1ml | 03052 | 04/2017 |
| PLEO-EX    | 5X | Drops         | 10ml     | 07011 | 12/2015 |
| PLEO-EX    | 5X | Drops         | 10ml     | 09043 | 03/2018 |
| PLEO-EX    | 3X | Suppositories | 10pcs    | 2011  | 12/2015 |
| PLEO-EX    | 3X | Suppositories | 10pcs    | 2081  | 07/2016 |
| PLEO-EX    | 3X | Suppositories | 10pcs    | 3063  | 05/2018 |
| PLEO-EX    | 3X | Suppositories | 10pcs    | 1013  | 02/2018 |
| PLEO-STOLO | 6X | Drops         | 10ml     | 08060 | 05/2015 |
| PLEO-STOLO | 6X | Drops         | 10ml     | 07119 | 08/2014 |
| PLEO-STOLO | 6X | Drops         | 10ml     | 03043 | 05/2018 |

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