Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: September 5, 2012

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

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

SUBJECT: Sun Pharmaceutical Industries, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; One lot of Nimodipine Capsules, 30 mg due to the presence of crystals of nimodipine within the capsule solution of this lot as identified by a customer complaint; 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 crystallization of the nimodipine fill material in the capsule could adversely affect the product's bioavailability. Although clinical health implications are unknown, use of the product when the nimodipine has crystallized in the capsule may be of great clinical significance. The product may no longer be bioequivalent and may potentially affect patients who are being treated for a medical emergency. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

****

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.

Sun Pharmaceutical Industries, Inc. Issues Nationwide Voluntary Recall of One Lot of Nimodipine Capsules due to Crystallization of the Fill Material

Contact
Consumer:
Thomas Versosky
(313) 556-4150

Robert Kurkiewicz
(800) 818-4555
1-800-967-5952

FOR IMMEDIATE RELEASE - September 4, 2012 - Sun Pharmaceutical Industries, Inc. (Sun Inc) announced today that it is voluntarily recalling from users one lot of Nimodipine Capsules, 30 mg, marketed by Caraco Pharmaceutical Laboratories, Ltd. Sun Inc. commenced the recall as a precautionary measure due to the presence of crystals of nimodipine within the capsule solution of this lot as identified by a customer complaint. No adverse events have been reported at this time.

Nimodipine Capsules, 30 mg, are used to decrease problems due to subarachnoid hemorrhage (bleeding in the brain). Nimodipine capsules 30 mg are clear yellow solution filled in oblong opaque light yellow softgel capsules, imprinted "135" in black ink. The product is supplied in unit dose blisters of 30 and 100, as described below. The affected product was distributed nationwide between January 19, 2012 and April 24, 2012

The crystallization of the nimodipine fill material in the capsule could adversely affect the product's bioavailability. Although clinical health implications are unknown, use of the product when the nimodipine has crystallized in the capsule may be of great clinical significance. The product may no longer be bioequivalent and may potentially affect patients who are being treated for a medical emergency.

As a precautionary measure, Sun Inc is recalling the following lot numbers to the consumer level to minimize any potential risk to patients

Lot Number: 3305.039A, NDC Number: 57664-135-65 (Unit Dose Blisters of 100 (25x4))

Lot Number: 3305.039B, NDC Number: 57664-135-64 (Unit Dose Blisters of 30 (5x6))

The recalled capsules were manufactured for Sun Inc by Pharmaceutics International, Inc. This recall is being conducted with the knowledge of the Food and Drug Administration.

Patients and healthcare providers using Nimodipine Capsules, 30 mg, with one of the above lot numbers should discontinue use of the product and should contact the following number for more information about the recall: Inmar Inc. at 1-800-967-5952 (Option 1 then Option 3). Representatives are available Monday through Friday, 8 AM to 5 PM EST.

Patients using Nimodipine Capsules, 30 mg, who have medical questions, should contact their healthcare provider for additional instructions or guidance.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program 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: . [2]www.fda.gov/MedWatch/getforms.htm[3] Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178