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:** August 2, 2010

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

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

**SUBJECT:** Lundbeck Inc. Recall

**SUGGESTED ACTION:** **Unclassified Recall; Two lots of NeoProfen® (ibuprofen lysine) Injection that failed to meet a visible particulate quality requirement; Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the products being recalled were distributed in the State of Indiana. Notification of the recall and resulting product shortage has been sent to all wholesalers who have received these lots, all hospital pharmacies, and prescribing neonatologists. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.**

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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.

## Lundbeck Inc. Announces the Voluntary Nationwide Recall of Two Lots of NeoProfen® (ibuprofen lysine) Injection Recall will Result in Temporary Product Shortage

**Company Contact:**
Sally Benjamin Young,
847-282-5770

**FOR IMMEDIATE RELEASE** - July 30, 2010 - Lundbeck Inc. has voluntarily recalled two lots of NeoProfen® (ibuprofen lysine) Injection that failed to meet a visible particulate quality requirement. These two lots are the only lots currently available to prescribers and therefore the recall will result in a temporary drug shortage. This voluntary recall is the result of the company's inspections of the two product lots of NeoProfen.

The NeoProfen recall, NDC 67386–122-52, includes product lots 1734991 (expiration date: April, 2011) and 1922319 (expiration date: March, 2012).

NeoProfen is a non-steroidal anti-inflammatory therapy indicated to close a clinically significant patent ductus arteriosus (PDA) in premature infants weighing between 500 and 1500 g, who are no more than 32 weeks gestational age when usual medical management (e.g., fluid restriction, diuretics, respiratory support, etc.) is ineffective.

To date, the company has not received adverse event reports or product complaints attributable to visible particulates from any lot of NeoProfen, including the lots that are being recalled. Particulate matter has the potential to obstruct blood vessels which could induce pulmonary emboli or activate platelets and/or neutrophils to induce anaphylactic reactions. Other adverse effects associated with intravenous injection of particulate matter include foreign body granulomas, and local irritation of blood vessels. The potential adverse events resulting from the use of a sterile injectable product with particulates can be very serious and potentially fatal. As such, the company is conducting a voluntary recall as a safety precaution, and will continue to closely monitor for reports of adverse drug reactions and product complaints.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Notification of the recall and resulting product shortage has been sent to all wholesalers who have received these lots, all hospital pharmacies, and prescribing neonatologists.

For medical information questions about NeoProfen, please call 866-402-8520 or email luinc-druginfo@lundbeck.com. Product complaints related to NeoProfen should be reported to 800-455-1141 (phone), Monday to Friday from 8:00 a.m. to 5:00 p.m. central time, 847-282-1003 (fax), or luinc_safety@lundbeck.com.

Any adverse events that may be related to the use of these products should be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178 or by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787 or on the MedWatch website at http:www.fda.gov/safety/medwatch/default.htm[9].

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