



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 17, 2013

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

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

SUBJECT: Nephron Pharmaceuticals Corporation (NPC) [Drug]

AFFECTED

PRODUCT(S): Albuterol Sulfate Inhalation Solution, 0.083%, in the 25 count packaging configuration (NDC# 0487-9501-25). See the attached implicated lot list.

SUMMARY: Voluntary Recall; Nephron Pharmaceuticals Corporation (NPC) has initiated a voluntary recall of Albuterol Sulfate Inhalation Solution, at the retail level, as a precautionary measure, due to results from our internal monitoring processes. NPC is asking retailers to remove the affected lots from store shelves and is asking consumers to discontinue use and dispose of any product they may have that is included in this recall.

SUGGESTED

ACTION: Recommend notification of affected parties via phone, fax, or e-mail. NPC is ready to work with every affected customer to ensure that the recall is not disruptive for the supply of this important drug product. Consumers with questions may contact NPC at 1-800-443-4313 ext. 2292.

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.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

**Nephron Pharmaceuticals Corporation Announces Voluntary Recall of
Albuterol Sulfate Inhalation Solution, 0.083%**

Contact

Consumer:

1-800-443-4313 ext. 2292

recall@nephronpharm.com

FOR IMMEDIATE RELEASE - October 10, 2013 - Nephron Pharmaceuticals Corporation (NPC) has initiated a voluntary recall, at the retail level, as a precautionary measure, due to results from our internal monitoring processes. NPC is asking retailers to remove the affected lots from store shelves and is asking consumers to discontinue use and dispose of any product they may have that is included in this recall. This voluntary recall will affect the following product:

**Albuterol Sulfate Inhalation Solution, 0.083%, in the 25 count packaging configuration
(NDC# 0487-9501-25)**

Ten (10) lots have been identified as impacted by this recall:

**A3A33A, A3A33B, A3A34A, A3A35A, A3A36A, A3A37A, A3A38A, A3A40A, A3A41A, and
A3A42A**

NPC performs aseptic process simulation as part of our internal processes to assure product quality. All of the lots listed above met and passed NPC's quality specifications at the time of manufacture. NPC has received no reportable adverse drug events for any of the lots included in this recall. Nevertheless, in accordance with published guidance regarding aseptic processing simulation from the Food and Drug Administration (FDA), NPC has decided to initiate this recall as a precautionary measure.

No other NPC products or lots are impacted by this recall.

We are ready to work with every affected customer to ensure that the recall is not disruptive for the supply of this important drug product.

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