



**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:** January 3, 2011

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

**FROM:** <sup>ASG</sup> A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** The Ritedose Corporation Recall

**SUGGESTED**

**ACTION:** Unclassified Recall; 0.083% Albuterol Sulfate Inhalation Solution, 3 mL (in 25, 30, and 60 unit dose vials) are embossed with the wrong concentration of 0.5 mg/ 3 mL and therefore, represents a potential significant health hazard; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The product is packaged as a single use unit dose vials in a protective foil overwrap packaged in a shelf carton. Only the unit dose vials are incorrectly embossed as containing 0.5 mg/3 mL. The correct concentration of 2.5 mg/3 mL is labeled on the primary foil overwrap pouches and shelf cartons. This product was distributed nationwide and Puerto Rico. Detail information is not available at this time. In addition, if any recalled products are 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.

**The Ritedose Corporation Announces the Voluntary Nationwide Recall of  
0.083% Albuterol Sulfate Inhalation Solution, 3 mL Due to Mislabeled Unit Dose  
Vials**

**Contact:**  
The Ritedose Corporation  
803-935-3995  
recall@ritedose.com

**FOR IMMEDIATE RELEASE** - December 30, 2010 - The Ritedose Corporation is conducting a voluntary recall of 0.083% Albuterol Sulfate Inhalation Solution, 3 mL (in 25, 30, and 60 unit dose vials). This product is a prescription inhalation solution, administered via nebulization, for the treatment and maintenance of acute asthma exacerbations and exercise induced asthma in children and adults. This product is being recalled because the 2.5 mg/3 mL single use vials are embossed with the wrong concentration of 0.5 mg/ 3 mL and therefore, represents a potential significant health hazard. The following lot numbers manufactured by The Ritedose Corporation under NDC: 0591-3797-83, 0591-3797-30, and 0591-3797-60 are included in the recall: 0N81, 0N82, 0N83, 0N84, 0NE7, 0NE8, 0NE9, 0NF0, 0P12, 0P13, 0P46, 0P47, 0PF0, and 0S15. No other Albuterol formulations or products are included in this recall.

The product is packaged as a single use unit dose vials in a protective foil overwrap packaged in a shelf carton. Only the unit dose vials are incorrectly embossed as containing 0.5 mg/3 mL. The correct concentration of 2.5 mg/3 mL is labeled on the primary foil overwrap pouches and shelf cartons. This product was distributed nationwide and Puerto Rico.

Administration of this defective product could result in a range of potential health effects that spans from temporary and medically reversible to life threatening and death. There is significant concern that health professionals who read the incorrect embossed concentration may upwardly adjust the volume of product used resulting in an administered amount that is 5 times the recommended dose. In the hospital setting, the vials are often not accompanied by the rest of the packaging, making it more likely that such a dosing error could occur. Significant overdosing of a patient could lead to signs and symptoms of albuterol toxicity, which includes tremors, dizziness, nervousness, headache, seizures, angina, high blood pressure, low potassium levels, and rapid heart rates up to 200 beats/minute.

The Ritedose Corporation is working cooperatively with the U.S. FDA to implement a nationwide recall as quickly and efficiently as possible.

Consumers should immediately return the affected product to the place it was obtained (i.e. doctor's office, pharmacy, etc.). Wholesalers and retailers should return the product to the following address:

Total Product Destruction  
Attn: RECALL  
8025 Howard Street  
Spartanburg, SC 29303

For more information concerning this recall contact The Ritedose Corporation directly at phone: 803-935-3995 Monday through Friday 8am to 5 pm EST or by e-mail: [recall@ritedose.com](mailto:recall@ritedose.com).

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, or regular mail or by fax.

- **Online:** <http://www.fda.gov/MedWatch/report.htm><sup>9</sup>
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm><sup>10</sup>. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178