



**Market Withdrawal Issued for Stolen Lots of Albuterol Sulfate and
Ipratropium Bromide Inhalation Solutions**

Dear Valued Member:

On September 8, 2009, several lots of albuterol sulfate inhalation solution 0.083% and ipratropium bromide inhalation solution 0.02%, manufactured by Dey, L.P., might have been part of a shipment that was stolen in Tampa, Florida. The stolen product has not been recovered and may be dangerous to use, as the drugs may not have been stored and handled properly. The lots involved in this theft are affected by a recent market withdrawal issued by Dey, L.P.

While the U.S. Food and Drug Administration (FDA) is not aware of any reports of adverse effects, patients who use these respiratory medications are advised to check and see if any products purchased or received after September 8, 2009 are from one of the following lots:

Albuterol Sulfate Inhalation Solution

892,000 doses; all lots contain 3mL vials and display the brand-name "Dey"

- NDC # 49502-697-29, Lot number 9G04 (Expiration July 2011)
- NDC # 49502-697-61, Lot number 9FD8 (Expiration June 2011)
- NDC # 49502-697-61, Lot number 9FD9 (Expiration June 2011)
- NDC # 49502-697-61, Lot number 9FE1 (Expiration June 2011)

Ipratropium Bromide Inhalation Solution

432,000 doses; all lots contain 2.5mL vials and display the brand-name "Dey"

- NDC # 49502-685-31, Lot number F09089 (Expiration June 2011)
- NDC # 49502-685-62, Lot number C09119 (Expiration March 2011)
- NDC # 49502-685-62, Lot number C09120 (Expiration March 2011)

Patients should not use either albuterol sulfate inhalation solution 0.083% or ipratropium bromide inhalation solution 0.02% from any of the lots listed above. Patients should contact their pharmacy for a replacement or call Dey Customer Service at 1-800-527-4278. Patients should also notify their physician of any potential side effects they may have experienced from taking these stolen medications.

If you have not recently purchased or are not currently taking albuterol sulfate inhalation solution 0.083% or ipratropium bromide inhalation solution 0.02%, please disregard this letter. Our records may not be complete or your doctor may have discontinued this medication.

Sincerely,

Catalyst Rx



Market Withdrawal Issued for Stolen Lots of Albuterol Sulfate and Ipratropium Bromide Inhalation Solutions

The U.S. Food and Drug Administration (FDA) recently released warnings to users of albuterol sulfate and ipratropium bromide inhalation solutions, explaining that certain lots of these respiratory medications were stolen from their manufacturer and may have been released to the public. Certain lots of these medications are subject to a market withdrawal issued by the manufacturer, Dey, L.P.

Warning #1

On or around August 6, 2009, two complete lots of albuterol sulfate inhalation solution 0.083%, manufactured by Dey, L.P., were stolen in McKinney, Texas. As these two lots were not commercially available prior to the theft, no vial or carton of either lot is part of the legitimate pharmaceutical supply chain and are not part of the market withdrawal action. The medications involved in this theft have been identified as having the following National Drug Code (NDC) number and lot numbers:

35,760 cartons of 30 units each; all lots contain 3mL vials and display the brand-name "Dey"

- NDC # 49502-697-29, Lot number 9FE2 (Expiration June 2011)
- NDC # 49502-697-29, Lot number 9G01 (Expiration July 2011)

Warning #2

On September 8, 2009, several lots of ipratropium bromide inhalation solution 0.02% and albuterol sulfate inhalation solution 0.083%, manufactured by Dey L.P., might have been part of a shipment that was stolen in Tampa, Florida. The stolen product has not been recovered and may be dangerous to use as the drugs may not have been stored and handled properly. The lots involved in this theft are affected by the market withdrawal issued by Dey, L.P.

Patients who use these respiratory medications are advised to check and see if any products purchased or received after September 8, 2009 are from one of the following lots:

Albuterol Sulfate Inhalation Solution

892,000 doses; all lots contain 3mL vials and display the brand-name "Dey"

- NDC # 49502-697-29, Lot number 9G04 (Expiration July 2011)
- NDC # 49502-697-61, Lot number 9FD8 (Expiration June 2011)
- NDC # 49502-697-61, Lot number 9FD9 (Expiration June 2011)
- NDC # 49502-697-61, Lot number 9FE1 (Expiration June 2011)

Market Withdrawal Issued for Stolen Lots of Albuterol Sulfate and Ipratropium Bromide Inhalation Solutions (Continued)

Ipratropium Bromide Inhalation Solution

432,000 doses; all lots contain 2.5mL vials and display the brand-name "Dey"

- NDC # 49502-685-31, Lot number F09089 (Expiration June 2011)
- NDC # 49502-685-62, Lot number C09119 (Expiration March 2011)
- NDC # 49502-685-62, Lot number C09120 (Expiration March 2011)

While the FDA is not aware of any reports of adverse effects, patients in possession of a stolen medication should discontinue their use immediately and contact their pharmacy for a replacement or call Dey Customer Service at 1-800-527-4278. Patients should also notify their physician of any potential side effects they may have experienced from taking these stolen medications.

As part of our pharmacy benefit management services, Catalyst Rx partners with clients, members, physicians, and pharmacies to provide updates regarding medication safety issues, industry news and changes to product availability. Catalyst Rx will continue to carefully monitor the situation and provide updates as appropriate. If you have questions, please call the Catalyst Rx Clinical Department at 702-869-4600.

References:

http://www.dey.com/Pressroom/News_090109.asp

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182846.htm>