



Schering/Key **Press Release**

SCHERING/KEY ISSUES NATIONWIDE RECALL OF FIVE LOTS OF VANCERIL DOUBLE STRENGTH INHALATION AEROSOL CONVENIENCE PACK

KENILWORTH, N.J., Dec. 2, 1999 – Schering/Key Pharmaceuticals is voluntarily conducting a nationwide recall of five lots of VANCERIL 84 mcg DOUBLE STRENGTH (beclomethasone dipropionate, 84 mcg) Inhalation Aerosol Convenience Pack, a prescription medication for the maintenance treatment of asthma. The company is taking this action because it has determined that a number of canisters in the five lots listed below may not contain active drug. Schering/Key is advising that the matter should be considered very serious and one that merits immediate attention. Patients using an affected canister without active drug would be expected to experience a lack of effectiveness which may result in increased asthma symptoms, need for other asthma medications, emergency room visits or hospitalization. Because of the nature of the problem, a patient cannot determine whether they have an affected metered dose inhaler (MDI) just by actuating their MDI. An affected MDI may appear to emit an aerosol even if it does not contain active drug.

The recall affects lots Nos. 9-DMT-157, 9-DMT-158, 9-DMT-160, 9-DMT-161 and 9-DMT-163, which were distributed by Schering/Key in November 1999. The inhalers have an expiration date of July 2000. The lot number and expiration date appear on either the top or bottom flaps of the package and on the canister label. No other lots of VANCERIL 84 mcg DOUBLE STRENGTH Inhalation Aerosol Convenience Pack are involved. The recall is being conducted with the knowledge of the U.S. Food and Drug Administration. There have been no reported medical adverse events related to the recalled lots.

The recall is being extended to individual patients, pharmacies and direct-account customers such as wholesalers and chain drug stores. Direct-account customers have been asked to return any units from the subject lots on hand and to request that their customers return any units from the subject lots to them. Patients who have had prescriptions for VANCERIL 84 mcg DOUBLE STRENGTH Inhalation Aerosol Convenience Pack filled since November 1999 are advised to check the lot numbers and return any inhalers from the subject lots to the pharmacy for free.

replacement. Any questions regarding the recall should be directed to the Recall Services Center (toll free) at 1-800-621-9760.

The cause of the problem has been identified as inadequate batch start-up practices that occurred for a short period during filling of the subject lots. The company has taken corrective actions to prevent a recurrence.

Schering/Key Pharmaceuticals is a business unit of Schering Laboratories, the U.S. pharmaceutical marketing arm of Schering-Plough Corporation (NYSE: SGP) of Madison, N.J., a research-based company engaged in the discovery, development, manufacturing and marketing of pharmaceutical products worldwide.

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