

# Compliance Alert

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April 6, 2006

***Compliance Alert, provided by Group Benefit Services, gives you the most up to date information regarding industry news as well as legislation and regulatory activities affecting your health plan.***

## TOPIC: FORMULARY UPDATE FROM ESI - FLONASE®

### Issue

On February 22, 2006, Roxane Laboratories received approval from the U.S. Food and Drug Administration (FDA) for its AB-rated generic to Flonase® (fluticasone propionate) nasal spray. After a short delay, Roxane's generic, along with a second generic from Par Pharmaceuticals, became available on March 6, 2006.

Now that generic Flonase is established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand product Flonase from Express Scripts formularies, replacing it with generic fluticasone nasal spray products. This procedure is being enacted because Flonase is marked with an '\*' on the formularies, indicating a potential conversion.

### Take-Away Points

- Generic fluticasone nasal sprays are AB-rated generics to Flonase® and are now available in the marketplace.
- The brand-name product, Flonase®, will be converted to non-formulary status on May 1, 2006.
- This procedure is being enacted because Flonase® is marked with an '\*' on the formularies, indicating a potential for conversion.

***This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.***

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In addition to Flonase®, several other drugs are scheduled to lose patent protection in 2006. The drugs listed in the table below will also be designated as "non-formulary" when generics are established in the market. However, keep in mind that although a key drug patent expires, generic products are not always readily available. There are many issues that may delay their availability, including ongoing litigation, final approval from FDA, and additional patents and granted exclusivities.

Adderall XR (amphetamine salts - Shire) - ADHD – Litigation  
Allegra® D (fexofenadine - sanofi-aventis) - Allergies – Litigation  
Concerta (methylphenidate, e.r. - McNeil PPC) – ADHD – Litigation  
Ditropan XL (oxybutynin, e.r. - Ortho McNeil) - Overactive Bladder – Litigation  
Emadine (emadastine - Alcon) - Ophth. Antiallergic – Expired  
Metadate CD (methylphenidate e.r. - UCB) – ADHD – Litigation  
Metrogel (metronidazole 0.75% gel - Galderma) - Topical antibiotic - June 6, 2006  
Proscar (finasteride - Merck) – Prostate - June 19, 2006  
Skelaxin (metaxalone - King) - Muscle Relaxant – Litigation  
Toprol XL (metoprolol, e.r. - AstraZeneca) - Blood pressure – Litigation  
Uniphyl (theophylline, c.r. - Purdue Frederick) - Asthma/COPD – Expired  
Wellbutrin XL (bupropion, e.r. - GlaxoSmithKline) – Depression – Litigation  
Zocor (simvastatin - Merck) – Cholesterol - June 23, 2006  
Zofran (ondansetron - GlaxoSmithKline) - Nausea/vomiting - December 23, 2006  
Zoloft (sertraline - Pfizer) – Depression - June 30, 2006  
\*Generics not yet available

***If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.***

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