



### **ANDA (GENERIC) DRUG APPROVALS**

To find all Generic Approvals and Tentative Approvals, you can search Drugs@FDA, using the "[Drug Approval Reports by Month](#)" feature. On the Drug Approval Reports page, select:

- "Original Abbreviated New Drug Approvals (ANDAs) by Month" for Generic Approvals
- "Tentative Approvals by Month" for Tentative Approvals

New approvals and tentative approvals are added to Drugs@FDA Reports on a daily basis, so you can run the reports every day to find the latest approvals

**Source:**

<http://www.fda.gov/Drugs/Development/ApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/>

**COMMENTS:** Several people have asked where to look for this information.

### **INHALER NEWS**

For further explanation about the increased cost of inhalers, please continue to read.

The [U.S. Food and Drug Administration](#) (FDA) in April 2005 mandated that all (including salbutamol) inhalers containing [chlorofluorocarbons](#) (CFCs) were prohibited in the United States as of December 31, 2008. CFC inhalers had previously been given "essential use" status, exempting it from a CFC-production ban, however in accordance with the [Montreal Protocol](#) they were phased out; in many other countries patients have been transitioned to non-CFC based inhalers using [hydrofluoroalkane](#) (HFA) propellant.

One drawback of this transition to HFA inhalers is that, due to patent restrictions, all HFA salbutamol inhalers are "brand-name" (ProAir, Proventil, and Ventolin). They cost approximately \$20 more per inhaler than generic CFC salbutamol inhalers. **Generic HFA salbutamol inhalers are not expected on the United States market until 2012 due to existing patents.**

**COMMENTS:** This is not a new issue, but people continue to ask why it is happening. Unfortunately, there is no cost relief until 2012 at the earliest.

### **MRSA LEADS TO WORSE OUTCOMES, STAGGERING EXPENSES FOR SURGICAL PATIENTS**

- Patients with surgical site infections due to MRSA were 35 times more likely to be readmitted and seven times more likely to die within 90 days compared to uninfected surgical patients
- Patients with surgical site infections also required more than three weeks of additional hospitalization and accrued more than \$60,000 in additional charges.
- Most of the outcomes for MRSA compared to MSSA were worse, as anticipated; however, the finding that methicillin-resistance contributed to longer hospital stays and increased hospital charges but did not increase the risk of mortality was surprising to the researchers.
- Patients with surgical site infections due to MRSA compared to MSSA on average required six more days of hospitalization and incurred \$24,000 in additional charges.

**COMMENTS:** Not surprisingly, MRSA infections cost more. The first approach is prevention. Review your hospital network to ensure that they have MRSA prevention as well as treatment protocols.

### **PRO PHARMA ANNOUNCES A NEW BLOG –**

## **Meet the Professor**

**Craig Stern, PharmD, MBA President, Pro Pharma Pharmaceutical Consultants, Inc**

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We discuss changes in AWP, pharmacy practice, market trends, etc.

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Discuss areas of interest regarding medications, pharmacy benefits, clinical pharmacology, etc.

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**Pro Pharma Pharmaceutical Consultants, Inc. has assisted Payers and Providers for over 24 years to Maintain Quality while Controlling Costs.**