The absence of a trade name does not equal a generic drug

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Have you always assumed a drug product marketed without a proprietary (brand) name to be a generic drug? If your answer is Yes, you may have inadvertently substituted and dispensed products that are not therapeutically equivalent. For example, the drug product albuterol sulfate HFA, manufactured by IVAX, was approved without a proprietary name on Oct. 29, 2004, under NDA 21-457. Since the IVAX albuterol sulfate HFA product is labeled with only the established (generic) name, one could easily assume this is a generic version of one of the other two currently marketed albuterol sulfate HFA products: Proventil HFA and Ventolin HFA.

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Although all three products contain the same active ingredient and propellant (HFA), they are not substitutable products. Differences in excipients such as oleic acid and alcohol—in addition to actual differences in device components, such as the canister and size of valve—may affect performance, resulting in different clinical responses.

Confusion may also arise when drug products are listed incorrectly in drug databases. For example, First Data Bank and Medispan list IVAX albuterol sulfate HFA as a generic drug. Additionally, in clinical practice various formularies may consider all three brand-name products as generics for reimbursement purposes.

In order to determine and ensure therapeutic equivalency of drug products, we refer pharmacists to the 25th edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, better known as the Orange Book, at **www.fda.gov/cder/ob**. The Orange Book designates drugs based on their therapeutic equivalence to other pharmaceutically equivalent products. Products that are designated 'A' are those for which actual or potential bioequivalence has been resolved with adequate evidence supporting bioequivalence. Products that are designated 'B' are those for which actual or potential bioequivalence problems has not been resolved by adequate evidence of bioequivalence. The three approved albuterol sulfate HFA products are designated 'BX,' meaning they are not substitutable for each other. Drugs with a BX rating are "presumed to be therapeutically inequivalent until the agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence."

In summary, it should not be assumed that all drug products marketed only with an established name are generic drugs. As an additional safety measure, ensure the therapeutic equivalence of each product prior to adding or substituting drugs on your product formulary to avert potential clinical consequences because of inappropriate product substitution.

References are available upon request.

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