Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Medicis Announces Voluntary Recall of Solodyn® (minocycline HCL, USP) 90 Mg Tablets, Extended Release; Lot Numbers B080037 and B080038 Due to Product Mix-Up

Contact:
Stericycle Customer Service
1-888-656-6381

FOR IMMEDIATE RELEASE -- SCOTTSDALE, Ariz. -- May 16, 2008 -- Medicis today announced that the Company is voluntarily recalling lot numbers B080037 (Exp: 12/09) and B080038 (Exp: 12/09) of the antibiotic SOLODYN® (minocycline HCl, USP) Extended Release Tablets, 90 mg, 30-count bottles (NDC 99207-461-30). Medicis has received a report that one bottle in lot number B080037 contains AZASAN® (azathioprine tablets) 75 mg (NDC 65649-231-51) instead of SOLODYN® (minocycline HCl, USP) Extended Release Tablets, 90 mg. AZASAN® is an immuno-suppressive agent used in transplant patients to prevent kidney rejection and for the treatment of rheumatoid arthritis. Taking AZASAN® instead of SOLODYN® presents a health hazard and safety risk to patients. Side effects associated with the use of AZASAN®, particularly in the elderly, include mylosuppression (decrease in the number of red and white blood cells and platelets), infection, bleeding, chills, nausea, vomiting and diarrhea. Joint and muscle pain are also common side effects. Unanticipated interactions with other drugs may also lead to serious adverse events. SOLODYN® is manufactured by AAIPharma, Inc. under contract to Medicis. The two lots were manufactured during February 2008. The recall is limited to these lots, and ample supplies of SOLODYN® remain on the market.

Any inquiries related to this recall should be addressed to Stericycle Customer Service at 1-888-656-6381 with representatives available Monday through Friday, 8 a.m. to 11 p.m. EST. For any medical information inquiries or to report an adverse event related to this recall, contact Medicis at 1-800-900-6389 with representatives available 24 hours a day, 7 days a week.

Health care professionals may continue to prescribe the Medicis brand SOLODYN®.
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This recall is being conducted in cooperation with the contract manufacturer of the products and with the knowledge of the FDA.

Any adverse reactions experienced with the use of this product, and/or quality problems, also may be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

SOLODYN is a registered trademark of Medicis Pharmaceutical Corporation. AZASAN is a registered trademark of AAIPharma, Inc.

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