

Generic Coreg® Approved by FDA

September 6, 2007 -- Rockville, MD -- The U.S. Food and Drug Administration today approved the first generic versions of Coreg (carvedilol). Coreg is a widely used medication that is FDA-approved to treat high blood pressure, mild to severe chronic heart failure and left ventricular dysfunction following a heart attack.

"The agency's Office of Generic Drugs ensures that generic drugs are safe and effective through a rigorous scientific and regulatory process," said Gary J. Buehler, director, FDA's Office of Generic Drugs. "Generic drugs, which use the same active ingredients as brand-name drugs and work the same way, offer alternatives to Americans in choosing their prescription drugs."

Carvedilol tablets in four strengths (3.125 milligrams, 6.25 milligrams, 12.5 milligrams and 25 milligrams) are manufactured by multiple generic drug companies. The following company's applications were approved today: Actavis Elizabeth LLC; Apotex Inc.; Aurobindo Pharma Limited; Caraco Pharmaceutical Laboratories Limited; Dr. Reddy's Laboratories; Glenmark Pharmaceuticals Limited; Lupin Limited; Mylan Pharmaceuticals Inc.; Ranbaxy Laboratories Ltd.; Sandoz Inc.; Taro Pharmaceutical Industries Ltd.; TEVA Pharmaceuticals USA; Watson Laboratories Inc.; and Zydus Pharmaceuticals USA Inc.

The labeling of the generic products may differ from that of Coreg because parts of the Coreg labeling are protected by patents and/or exclusivity.

Source: Food and Drug Administration