FDA approves a new beta blocker

December 18 2007

The U.S. Food and Drug Administration has approved Bystolic, a beta blocker, for the treatment of high blood pressure. Bystolic (nebivolol) is a new drug not previously approved for use in the United States.

Beta blockers are a well-established class of medications that reduce blood pressure by reducing the force with which the heart pumps, the FDA said. Nearly 1-in-3 adults in the United States suffers from hypertension, which can increase the risks for stroke, heart failure, heart attack, kidney failure, and death.

The FDA said the safety and efficacy of Bystolic was assessed during three randomized, double-blind, multi-center, placebo-controlled clinical trials that ran for up to three months. A fourth placebo-controlled clinical trial demonstrated additional blood pressure-lowering effects when Bystolic was given with up to two other antihypertensive medications in patients with inadequate blood pressure control.

More than 2,000 people received Bystolic during the trials, the FDA said, with the most common side effects reported being headache, fatigue, dizziness and diarrhea.

Mylan Bertek Pharmaceuticals Inc. of Research Triangle Park, N.C., is the sponsor of Bystolic. New York City-based Forest Laboratories Inc. owns the rights for marketing of the drug.