

New Asthma Inhaler Approved for Children

By LINDA A. JOHNSON Associated Press February 4, 2008

TRENTON, N.J. -- A new inhaled steroid treatment for preventing asthma attacks in young children has been approved by the Food and Drug Administration, the drugmaker Schering-Plough Corp. said Monday.

Its Asmanex Twisthaler is the first once-a-day, inhaled corticosteroid medicine for asthma - the most common chronic condition among children - that can be taken by children as young as 4.

The Kenilworth-based company got FDA approval two years ago to sell the product as a maintenance treatment to prevent asthma flare-ups in adults and children 12 and older. The dosage for children aged 4 to 11, 110 micrograms, is half the adult dose.

Competing products are approved for children as young as 6, or must be taken more times a day.

Asthma afflicts 7 percent to 10 percent of U.S. children under 18. It is blamed for more than 14 million missed school days and nearly 1 million emergency room visits by children each year, according to the Asthma and Allergy Foundation of America.

Flare-ups of the sometimes-deadly lung disease are triggered when allergens such as pollen or irritants like smoke aggravate airways, causing trouble breathing, wheezing, coughing and tightness in the chest.

Inhaled corticosteroids are now the cornerstone of asthma care, the first treatment given newly diagnosed patients because they go straight to the lungs rather than through the bloodstream like the ingredients in pills, said Mike Tringale, spokesman for the foundation. He said each new treatment is helpful.

"The broader sort of palette that a physician has to work with, the more customized their treatments can be, and that's a good thing," he said.

The new product should be available in the second half of 2008, said Schering-Plough spokeswoman Lisa Ellen.

Unlike standard inhalers, the Twisthaler does not have a propellant. It is activated when the patient puts the end in the mouth and takes a breath. A counter shows how many doses are left.

A small study in children 4 to 11 showed the Twisthaler reduced day and nighttime symptoms, plus "interruptions" of daily life such as emergency medical visits or missing school, significantly more than an inhaler with no active ingredient.

Asmanex has some significant side effects, like other inhaled corticosteroids: It can slow growth rate in kids, cause fungal infections of the mouth and increase risk of glaucoma or cataracts. More commonly, it can cause headaches, sore throat, respiratory infection, upset stomach and muscle, bone or back pain.