

news release

September 20, 1999

'ACCOLATE' APPROVED BY FDA FOR CHILDREN WITH ASTHMA SEVEN YEARS OF AGE AND OLDER

A new paediatric formulation of the popular asthma medication, 'Accolate', has received approval from the U.S. Food and Drug Administration (FDA) for use in patients as young as seven years of age. The product will be available in a 10-milligram, non-flavored mini-tablet specifically designed for children. Recommended dosing is one 10-mg mini-tablet twice daily, even during symptom free periods.

Since 1996, 'Accolate' has helped control symptoms for asthma sufferers 12 years of age and older. In the U.S., 'Accolate', the most widely prescribed antileukotriene drug, has been prescribed more than 5 million times for the preventive and chronic treatment of asthma. 'Accolate' is now approved in 60 countries worldwide.

"The new paediatric indication for 'Accolate' is very important because it offers a new and safe preventative asthma treatment option for children," said Kathy L. Lampl, M.D., Medical Director of Asthma & Allergy Associates, Rockville, Maryland. "Although there is no cure for asthma, parents can now help control their child's asthma all through the day and night with a convenient oral tablet."

Asthma in children is becoming more and more prevalent and asthma is the most common chronic medical problem affecting young adults.¹ An estimated 17 million Americans suffer from asthma,² including more than five million children under the age of 18.³

Since 1980, asthma in children under the age of five has jumped 160 percent.¹ Asthma is the leading cause of school absence due to chronic illness and children with asthma miss 10 million school days each year.¹ These children miss an average of twice as many school days as other children. Asthma can be triggered by numerous factors, including pollution, cigarette smoke, house dust mites, cats, cockroaches, and moulds. Although no cure exists for asthma, it can be effectively controlled.

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¹ Stapleton, Stephanie, "Asthma rates hit epidemic numbers; experts wonder why." *American Medical News;* May 11, 1998, p4.

² Centers for Disease Control and Prevention, Asthma Prevention Program of the National Center for Environmental Health, At-a-Glance, 1998.

³ Centers for Disease Control and Prevention, "Surveillance for Asthma—United States, 1960-1995." U.S. Department of Health and Human Services; Vol.47, No. 22-1, 4/24/98.