

PRNewswire

FDA Approves alli(TM) (orlistat 60 mg capsules) Over-The-Counter

Wednesday February 7, 4:34 pm ET

An Innovative and Honest Approach to Weight Loss

Combines a Safe and Effective Product With An Innovative Personalized Support Program

PITTSBURGH, Feb. 7 /PRNewswire-FirstCall/-- GlaxoSmithKline [NYSE:GSK] Consumer Healthcare announces today that the U.S. Food and Drug Administration (FDA) approved the weight-loss product orlistat 60 mg capsules for over-the-counter (OTC) use in the United States. GSK Consumer Healthcare will market OTC orlistat under the brand name alli(TM) (pronounced AL-eye). Approved for use by overweight adults in conjunction with a reduced-calorie, low-fat diet, alli helps people lose 50 percent more weight than with diet alone. alli is the only FDA-approved weight-loss product available to consumers without a prescription, and it is the first clinically-proven over-the-counter product to be combined with a comprehensive support program. alli is expected to be available in stores nationwide by summer 2007. This approval marks the start of an educational program that includes a series of resources online at myalli.com.

GSK Consumer Healthcare selected alli as the brand name because it conveys the concept of partnership with consumers in their weight-loss efforts. Consumers spend billions of dollars each year on fad diets, unproven miracle pills, and potentially unsafe weight-loss supplements that may not work. alli is the clinically proven option to these hyped, quick-fix products that mislead overweight adults away from weight-loss strategies that are backed by medical science. With alli, consumers have access to an individually tailored online action plan that provides support and the necessary tools to help them lose 50 percent more weight than with diet alone.

Caroline Apovian, M.D., Director of the Center for Nutrition and Weight Management at Boston Medical Center welcomed the FDA decision. "I applaud the alli program for stressing the importance of a reduced-calorie, low-fat diet in conjunction with a weight-loss medicine proven to be safe and effective. This lines up with research that shows even modest, gradual weight loss provides significant health benefits." Apovian adds, "More and more people each year -- now two-thirds of all American adults -- are overweight or obese and still gaining weight.

Desperate to lose this excess weight, people resort to all types of extreme methods that promise everything and deliver no real results. Extremely restrictive diets are unrealistic to maintain, even for a couple of weeks. Dieters end up gaining more weight than they initially lost. It's time consumers readjust their thinking to realize positive results."

Why alli is Different

Unlike other products on store shelves, alli is a proven medicine with a comprehensive support program. To help consumers get off to a successful start, the alli package will include Welcome and Companion Guides, a Guide to Healthy Eating, a Daily Journal, a Calorie and Fat Counter, Quick Fact Cards, and free access to an individualized online action plan at myalli.com.

"With alli, we're excited to offer a revolutionary approach to weight loss," says Steven L. Burton, Vice President, Weight Control, GlaxoSmithKline Consumer Healthcare. "alli is more than a pill -- it's a comprehensive program that works in conjunction with a sensible diet to increase weight loss. Because weight loss doesn't happen overnight, we're starting to educate consumers now about the importance of realistic expectations, gradual weight loss and lifestyle changes. That's the way to see results, and with alli, we know they can do it."

Starting today, GSK Consumer Healthcare will gear up production to have the product ready for shipment and in stores by the summer. The company is using this period to build awareness and understanding about the product and its intended user -- with the message -- alli is not for everyone. It's for the committed consumer who can follow a reduced-calorie, low-fat diet. For this consumer, alli will provide a unique, proven approach to weight loss, offering straight talk, educational tools and an online support program -- myalli.com.

How to Use alli

alli, the only FDA-approved weight-loss product soon to be available without a prescription, is indicated for weight loss in overweight adults 18 years and older when used along with a reduced-calorie, low-fat diet. The recommended dose of alli is one 60 mg capsule three times a day with meals containing fat.

Taken at meal-time, alli works by blocking about 25 percent of the fat in the food a person eats. Because of the way it works, alli must be used in conjunction with a reduced-calorie, low-fat diet containing about 15 grams of fat per meal. The guides and information supplied in the alli package help the consumer to control the amount of fat in their meals, and to follow an appealing, reduced-calorie, low-fat diet. Consuming a meal with too much fat, while taking alli, can result in bowel changes such as having an urgent need to use the bathroom. These changes, called treatment effects, generally occur in the first weeks of treatment, are not harmful, and can be managed by following the recommended diet with about 15 grams of fat per meal. Users should take a multivitamin once a day, at bedtime, because alli can reduce the absorption of some vitamins.

Safety and Efficacy

alli (60 mg orlistat capsules) is safe and effective when used as directed. As the most extensively studied weight-loss medication on the market, the safety and efficacy of orlistat is very well established. A higher dose of orlistat has been marketed as the prescription drug Xenical® (orlistat 120 mg capsules) in the U.S. since 1999 and is supported by nine years of worldwide use in 145 other countries. Orlistat experience in more than 25 million patient treatments and more than 100 clinical studies with more than 30,000 patients is unprecedented. One of these studies with Xenical is the four-year landmark XENDOS trial conducted by Roche, its inventor and manufacturer. This study is the longest study ever conducted for a weight-loss medicine.

Xenical (orlistat 120 mg capsules) will remain available by prescription for those who should be treated under the care of a physician. Xenical will continue to be manufactured and sold by Roche.

For more information on alli, go to myalli.com.

About Overweight and Obesity

Currently, approximately 65 percent of U.S. adults are overweight or obese, according to the National Institutes of Health. Research suggests that overweight individuals appear to be on the pathway to obesity.(i, ii) Overweight and obesity are associated with an increased risk of developing health problems such as hypertension, type 2 diabetes and heart disease.(iii) Factors that can contribute to overweight include an abundance of high-calorie foods, low levels of physical activity, behavior, environment, and genetics.(iv) Multiple studies have shown that a modest reduction in weight improves health outcomes significantly in overweight or obese patients.(v, vi)

About GlaxoSmithKline Consumer Healthcare

GSK Consumer Healthcare is one of the world's largest over-the-counter consumer healthcare products companies. Its more than 30 well-known brands include the leading smoking cessation products, Nicorette®, NicoDerm® CQ and Commit® as well as many medicine cabinet staples, including Abreva®, Aquafresh®, Sensodyne®, Tums® and Breathe Right®.

About GlaxoSmithKline

GlaxoSmithKline -- one of the world's leading research-based pharmaceutical and healthcare companies -- is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information visit: <http://www.gsk.com>.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in the Operating and Financial Review and Prospects in the company's Annual Report 2004.