

## The FDA Approves New Drug for Smoking Cessation

In May 2006, the Food and Drug Administration approved Chantix (varenicline tartrate) tablets to help cigarette smokers ages 18 and older stop smoking.

The drug received a priority review because of its significant potential benefit to public health. Chantix was reviewed in six months rather than the regular review time of 10 months, says Curt Rosebraugh, M.D., M.P.H., deputy director of the FDA's Office of Drug Evaluation II. "Chantix underwent priority review," Rosebraugh says, "because at the time the application was filed, a preliminary review of the efficacy studies indicated that smokers treated with Chantix may have a superior rate of smoking cessation compared to Zyban (bupropion), another currently approved product for smoking cessation."

Chantix acts at sites in the brain affected by nicotine and may help those who wish to give up smoking in two ways: by providing some nicotine effects to ease the withdrawal symptoms and by blocking the effects of nicotine from cigarettes if they resume smoking. Rosebraugh says, "If someone slips up, they would probably not have the reinforcement that they would normally get from smoking a cigarette."

According to the Centers for Disease Control and Prevention (CDC), an estimated 45 million adults in the United States smoke cigarettes, and more than 8 million of them have at least one serious illness caused by smoking.

"Tobacco use, particularly cigarette smoking, is the single most preventable cause of death in the United States and is responsible for a growing list of cancers as well as chronic diseases including those of the lung and heart," says Scott Gottlieb, M.D., the FDA's deputy commissioner for medical and scientific affairs. "The agency is committed to helping facilitate the development of products to help people quit smoking and improve their overall quality of life."

The effectiveness of Chantix in smoking cessation was demonstrated in six clinical trials, which included a total of 3,659 chronic cigarette smokers who were treated with varenicline. Five of the six studies were randomized, controlled clinical trials in which Chantix was shown to be superior to placebo in helping people quit smoking. These smokers had previously averaged 21 cigarettes a day for about 25 years.

In two of the five placebo-controlled studies, Chantix-treated patients were also more successful in giving up smoking than patients treated with Zyban. "Both studies had very similar results with approximately 44 percent of people taking Chantix having stopped smoking at the end of 12 weeks, compared with 17 percent of people who were taking placebo and 30 percent of people taking bupropion," Rosebraugh says. "Researchers followed study participants in both studies for a year and found that approximately 22 percent of people taking Chantix, 16 percent of people taking bupropion, and 10 percent of people taking placebo were still smoke-free at the end of the year."

The approved course of Chantix treatment is 12 weeks. Rosebraugh says that for the first three days, patients take 0.5 milligram (mg) once a day, followed by 0.5 mg twice a day for the next four days, and then 1 mg twice a day for the remainder of the treatment period. Patients who successfully quit smoking during Chantix treatment may continue with an additional 12 weeks of

treatment that further increases the likelihood of long-term smoking cessation.

"Cigarette smoking is a very difficult habit to break due in large part to nicotine dependence or addiction," says Steven Galson, M.D., director of the FDA's Center for Drug Evaluation and Research. "Chantix therapy has proven to be effective in smokers motivated to quit and will provide another tool for physicians to use for the millions of smokers who want to quit."

In clinical trials, the most common adverse effects of Chantix were nausea, followed by changes in dreaming, constipation, gas, and vomiting.

Chantix is manufactured and distributed by New York-based Pfizer Inc.

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