

FDA News

FOR IMMEDIATE RELEASE

November 9, 2007

Media Inquiries:

Susan Cruzan, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Approves Nonprescription Zyrtec-D for Allergies

The Food and Drug Administration (FDA) has approved Zyrtec-D (cetirizine HCl 5 mg and pseudoephedrine HCl 120 mg), an allergy drug, for nonprescription use in adults and children 12 years of age and older. This drug combines an antihistamine with a nasal decongestant.

Available as a prescription drug since 2001, Zyrtec-D is now approved as a nonprescription drug for the relief of symptoms due to hay fever or other upper respiratory allergies such as, runny nose, sneezing, itchy, watery eyes, itching of the nose or throat, and nasal congestion. Zyrtec-D is also for reducing swelling of nasal passages, for relief of sinus congestion and pressure, and for restoring freer breathing through the nose.

Hay fever and other allergies are the sixth leading cause of chronic disease, with about 50 million sufferers each year in the United States, according to the National Institute of Allergy and Infectious Diseases.

"The approval of this widely-used drug for nonprescription use will enable many people to have access to another effective treatment for their allergy symptoms," said Andrea Leonard-Segal, M.D., director, Division of Nonprescription Clinical Evaluation in the FDA's Center for Drug Evaluation and Research. "This approval reflects FDA's commitment to bringing prescription drugs to the over-the-counter market when they can be safely used without a prescription.

Zyrtec-D's common side effects include drowsiness, fatigue, and dry mouth. Sales of the drug are subject to restrictions in the Combat Methamphetamine Epidemic Act. This law places restrictions on the sale of products containing pseudoephedrine, such as limiting the amount that an individual can purchase, and imposing record keeping requirements on the retail establishments that sell the product. Zyrtec-D is distributed by McNeil Consumer Healthcare, Fort Washington, Pa.

For more information:

Allergies and Hay Fever Fact Sheet

www.fda.gov/womens/getthefacts/allergies.html

FDA Consumer Magazine: "Itching for Some Allergy Relief?"

www.fda.gov/fdac/features/2002/302_itch.html

#

[RSS Feed for FDA News Releases](#) [\[what is RSS?\]](#)

[Get free weekly updates](#) about FDA press releases, recalls, speeches, testimony and more.
