U.S. Food and Drug Administration
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FDA NEWS RELEASE

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FDA approves first generic capecitabine to treat colorectal and breast cancers

The U.S. Food and Drug Administration today approved the first generic version of Xeloda (capecitabine), an oral chemotherapy pill used to treat cancer of the colon or rectum (colorectal cancer) that has spread to other parts of the body (metastatic), and metastatic breast cancer.

Teva Pharmaceuticals USA has gained FDA approval to market generic capecitabine in 150 and 500 milligram strengths.

“Generic drugs are important options that allow greater access to health care for all Americans,” said Kathleen Uhl, M.D., acting director of the Office of Generic Drugs in the FDA’s Center for Drug Evaluation and Research. “This medication is widely used by people living with cancer, so it is important to have access to affordable treatment options.”

According to the National Cancer Institute, it is estimated that 1.6 million people in the United States will be diagnosed with and 580,000 will die of cancer in 2013. It is estimated that 142,820 people will be diagnosed with and 50,830 will die of cancer of the colon and rectum in 2013. An estimated 232,340 women will be diagnosed with and 39,620 women will die of cancer of the breast in 2013.

In the clinical trials for Xeloda, the most commonly observed adverse reactions included: diarrhea; vomiting; nausea; pain, redness, swelling, or sores in the mouth; hand-and-foot syndrome (pain, swelling, or redness of hands or feet that prevents normal activity); and fever or infection.

It is important that the prescriber know if the patient is also taking a medicine used to thin the blood,

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such as warfarin. Capecitabine could increase the effect of this medicine, possibly leading to serious side effects. Capecitabine has a boxed warning to alert health care professionals and patients about this risk.

Generic drugs approved by the FDA have the same high quality and strength as brand-name drugs. Generic drug manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs.

Information about the availability of generic capecitabine can be obtained from Teva.

For more information:

- **FDA: Understanding Generic Drugs (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm)**
- **National Cancer Institute: Comprehensive Cancer Information (http://www.cancer.gov/)**
- **Information on specific drug products, Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)**

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