Generic Zerit Approved in United States

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Three generic formulations of stavudine—originally marketed by Bristol-Myers Squibb (BMS) using the brand name Zerit—have been approved by the U.S. Food and Drug Administration (FDA) for use in both developing nations and the United States, according to an FDA announcement.

Stavudine is a nucleoside reverse transcriptase inhibitor (NRTI). Once quite popular in the United States, it is no longer commonly used due to side effects such as peripheral fat loss (lipoatrophy). In fact, U.S. and European treatment guidelines recommend against using stavudine because of the side effects. The drug is, however, one of the most commonly used antiretrovirals as first-line therapy in the developing world due to the low cost of existing generic versions there.

The three formulations approved include an oral and capsule formulation from Aurobindo Pharma and a capsule formulation from Hetero Drugs Limited from Hyberdad, India. The FDA has judged that the generics achieve similar drug concentrations in the body as BMS's brand name version. Because the patent and pediatric exclusivity protections by BMS have now expired, the generic formulations may now be sold in the United States.