Generic zidovudine in Capsule Form

This message corrects the previous (3/29/2006) notice of a tentative approval for the capsule dosage form of zidovudine to treat HIV/AIDS. While the generic formulation does qualify for consideration under the President's Emergency Fund for AIDS Relief (PEPFAR), because patents on the original formulations have expired, FDA has issued an approval for generic zidovudine capsules to be marketed in the United States. The tablet and oral solution dosage forms of zidovudine were previously approved for sale in the United States when the patent on those dosage forms expired in September 2005. The approval for the capsule formulation of the drug, which is manufactured by Aurobindo Pharma LTD. in Hyderabad, India, follows the expiration of GlaxoSmithKline's patent on its capsule form of the product marketed under the tradename Retrovir.

Zidovudine is in the class of drugs called nucleoside reverse transcriptase inhibitors (NRTIs), which help keep the AIDS virus from reproducing. This anti-retroviral drug is intended to be used with other anti-retroviral agents for the treatment of HIV-1 infection.

The agency's approval of zidovudine means that there are no existing patents and/or exclusivity preventing the approval of generic versions of this product. As with all FDA-approved generics, this product must meet all of FDA's manufacturing quality, and clinical safety and effectiveness standards for U.S. marketing.

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